

1. One cannot maintain a continuous exponentially decaying flow of medication which is required for the treatment of some disorders;

2. The absence of a continuous, controllably decaying outward flow from the pump outlet (such as a catheter) can result, due to the body's functioning, in the clogging of the outlet (or catheter) tip; and

3. The absence of flow resistance or restriction at the output allows the possibility of an inadvertently high medication flow rate into the body in the event of bellows pump runaway."

Page 4, ~~line 17~~, delete "entering" and replace therefore --being inadvertently released into--. This amendment was previously incorrectly requested for line 7.

In the Description of the Drawings:

Page 8, line 14, before "sample" insert --a--.

In the Description of the Invention:

Page 10, line 3, after "physician" insert ---.

Page 25, line 3, was incorrectly amended to place two commas after "interrogation" and no commas after "programming". The line to read correctly should have one comma after "programming" and one comma after "interrogation".

Page 27, line 6, has been incorrectly amended so that the numeral "400" now appears twice after "unit". The numeral 400 should only appear once after "unit" on this line.

In the Claims:

Kindly cancel all claims presently in the application, without prejudice, and replace therefor the following new claims 85 through 726;

8. CM 1 ~~85~~ A programmable infusion system for providing medication to a living body ^{of a patient} comprising:

P₁ an infusion apparatus for implantation in said living body, said apparatus including

P₂ a medication reservoir for storing selected medication,

P₂ means for infusing said selected medication stored in said medication reservoir into said living body, said infusion means having at least one remotely commandable operational characteristic,

P₂ command receiver means coupled to said infusion means for receiving command signals, and

P₂ means for telemetering operational information pertaining to said infusion apparatus out of said living body;

D1 P₁ command source means external to said living body for transmitting said command signals to be received by said command receiver means; and

P₁ means for receiving said telemetered operational information external to said living body.

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1 ~~86~~ A programmable infusion system in accordance with claim ~~85~~, wherein one of said command signals transmitted by said command source means comprises a signal which corresponds to a selected operational rate at which said infusion means will infuse said selected medication into said living body.

3
1 ~~87~~ A programmable infusion system in accordance with claim ~~85~~, wherein said command source and said telemetry receiving means are embodied in a patient programming unit external to said living body, said patient programming unit having a plurality of operational medication dose inputs each

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corresponding to a medication infusion rate selectable and requestable by the patient, said patient programming unit for selectively transmitting a command signal corresponding to a selected ^{one of} said medication dose ^{inputs} ~~input~~.

3 4
88. A programmable infusion system in accordance with claim 87, wherein said infusion apparatus further comprises electronic control means coupled to said infusion means and said command receiver means, said ~~electric~~ ^{electronic} control means ^{including means} for maintaining a history of the infusion rate at which said infusion means has operated, said ~~electronic~~ ^{including means} control means for precluding the infusion of said selected medication by said infusion means if said rate requested by said patient programming unit exceeds a predetermined safe medication infusion rate based on said maintained history.

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89. A programmable infusion system in accordance with claim 88, wherein said electronic control means is coupled to said telemetry means, said patient programming unit including means for indicating to said patient if said selected infusion rate exceeds said predetermined safe medication infusion rate, said ~~selective~~ ^{electronic} control means selectively sending a signal to said indicating means via said telemetry means and said telemetry receiving means, said telemetry receiving means being coupled to said indicating means.

3 6
90. A programmable infusion system in accordance with claim 87, wherein said patient programming unit further comprises annunciator means and visual display means for providing information regarding previously selected medication infusion rates, for indicating whether a proper programming of a presently requested infusion rate has been communicated to said command receiver, and for selectively providing information as to the time and rate of previously selected medication infusion.

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91. A programmable infusion system in accordance with claim 85, further comprising means for selectively supplying power to said command receiver means, said supply means being coupled to an external power source, said supply means being external to said living body, said infusion means being powered by an implanted power source.

⁸
92. A programmable infusion system, in accordance with claim 91, wherein said supply means provides an alternating field.

⁹
93. A programmable infusion system, in accordance with claim 92, wherein said infusion apparatus further comprises detector means for detecting said alternating field and for converting the same into electrical energy, said detecting means being coupled to said command receiver.

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¹⁰
94. A programmable infusion system in accordance with claim 93, wherein said infusion apparatus further comprises means for rectifying said electrical energy into a d.c. power signal.

¹¹
95. A programmable infusion system in accordance with claim 94, wherein said d.c. power signal is coupled to said implanted power source to effect the charging thereof.

¹²
96. A programmable infusion system in accordance with claim 94, wherein said telemetry means is coupled to said rectifier means and is powered by said d.c. power signal.

¹³
97. A programmable infusion system in accordance with claim 91, wherein said telemetry means is also supplied power by said supply means.

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¹⁴
98. A programmable infusion system in accordance with claim 91, further comprising means for selectively recharging said implanted power source, said recharging means being powered by said supply means.

¹⁵
99. A programmable infusion system in accordance with claim 85, wherein said infusion means comprises a fluid handling mechanism for delivering said selected medication, said operational information including information about the operation of said fluid handling mechanism.

¹⁶
100. A programmable infusion system in accordance with claim 99, wherein said fluid handling mechanism comprises means for pumping said selected medication.

¹⁷
101. A programmable infusion system in accordance with claim 100, wherein the amount of medication pumped by said pumping means is controlled by a pressure limit in said pump means.

¹⁸
102. A programmable infusion system in accordance with claim 100, wherein said pump means operates in a pulsatile mode.

¹⁹
103. A programmable infusion system in accordance with claim 102, wherein said pump means pumps a fixed volume of said selected medication each time said pump means is pulsed.

²⁰
104. A programmable infusion system in accordance with claim 100, wherein said pump means comprises variable volume means for storing said selected medication within said pump means, an increase in volume of said variable volume means permitting drawing of said selected medication into said pump means, a decrease in volume of said variable volume means permitting expulsion of said selected medication from said pump means.

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105. A programmable infusion system in accordance with claim 104, wherein said variable volume means comprises at least one flexible wall, movement of said ^{at least one} flexible wall varying the volume of said variable volume means, and means for moving said ^{at least one} flexible wall.

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106. A programmable infusion system in accordance with claim 105, further comprising spring means for urging said ^{at least one flexible} wall in a manner which decreases the volume of said variable volume means, the magnitude of the force applied to and stored by said spring means increasing as the volume of said variable volume means increases due to the displacement of said ^{at least one} flexible wall thereof by said moving means.

107. A programmable infusion system in accordance with claim 106, wherein said ^{at least one} flexible wall comprises a bellows assembly having mounted on one end thereof a plate, the other end of said bellows ^{assembly} being in communication with said selected medication, the walls of said bellows ^{assembly} serving as said spring means.

24
23-108. A programmable infusion system in accordance with claim 107, wherein said plate has a surface in contact with said selected medication when drawn into said variable volume means.

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24-109. A programmable infusion system in accordance with claim 108, wherein said bellows ^{assembly} is inhibited from moving said plate when the pressure (p) in said variable volume means exceeds the spring force (F) of said bellows ^{assembly} divided by the wetted area (A) of said surface of said plate in contact with said selected medication, that is when $p > \frac{F}{A}$.

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23-110. A programmable infusion system in accordance with claim 107, wherein ^{said plate is magnetizable, comprising} said moving means ~~comprises said plate being~~

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~~magnetisable~~ and a coil disposed proximate to said plate, said coil selectively radiating a pulsing magnetic field, pulsing of said coil causing said plate to be moved.

26 ²⁷ 111. A programmable infusion system in accordance with claim 110, wherein said plate comprises a permanent magnet.

23 ²⁸ 112. A programmable infusion system in accordance with claim 107, further comprising means for limiting the distance said plate can move in both ^{a a} ~~the~~ volume increasing direction and ^{a a} ~~the~~ volume decreasing direction.

20 ²⁹ 113. A programmable infusion system in accordance with claim 104, wherein said infusion means further comprises:

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D' P_i an interface pressure ^{valve} ~~valve~~ through which said selected medication enters said variable volume means from said medication reservoir, said interface pressure valve being normally closed;

P_i an outlet chamber which is in communication with said living body; and

P_i an outlet pressure valve located between said variable volume means and said outlet chamber, said outlet pressure valve being normally closed, an increase in volume of said variable volume means causing said interface pressure valve to open and medication to enter said variable volume means, a decrease in volume of said variable volume means causing said outlet pressure valve to open and said interface pressure valve to close, so as to permit medication to enter said outlet chamber as a pressure pulse.

24 ³⁰ 114. A programmable infusion system in accordance with claim 113, wherein said outlet chamber comprises an elastic wall having a fluidic capacitive effect on the flow of said selected

8 medication and a filter element through which liquid flow to the said ^{living living} ~~living~~ body is resisted, said elastic wall and said filter comprising a fluid resistance - capacitance arrangement with respect to said flow of said selected medication from said outlet chamber into said living body.

8 19 31 ~~102~~ 115. A programmable infusion system in accordance with claim ~~102~~, further comprising means for feeding said selected medication into said living body from said pump means in a flow which decays exponentially over time.

32 116. A programmable infusion system in accordance with claim ~~115~~, wherein said feeding means comprises a mechanical resistance (R) and a mechanical capacitance (C) circuit resulting in an exponentially decaying outflow of medication for each said fixed volume pulse.

D 33 117. A programmable infusion system in accordance with claim ~~104~~, wherein said infusion means further comprises an outlet chamber which is in communication with said living body, said pump means expelling said selected medication into said outlet ~~chamber,~~ ^{chamber,} and means for monitoring the operation of said pump means, said monitoring means being disposed in said outlet chamber and providing a signal in response to a pressure pulse in said outlet chamber caused by said pump means, said monitoring means being operably coupled to said telemetry means.

33 34 118. A programmable infusion system in accordance with claim ~~117~~, wherein said monitoring means comprises a pressure transducer.

33 35 119. A programmable infusion system in accordance with claim ~~117~~, further comprising first means for indicating the operation

of said pump means when a decrease in volume of said variable volume means is not followed by a signal from said monitoring means corresponding to a pressure pulse of said selected medication expelled into said outlet chamber, said first indicating means being operably coupled to said telemetry means.

8 36
120. A programmable infusion system in accordance with claim 119, further comprising second means for indicating the operation of said pump means when a signal is provided by said monitoring means absent a decrease in volume of said variable volume means ~~caused by said moving means~~, said second indicating means being operably coupled to said telemetry means.

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121. A programmable infusion system in accordance with claim 120, further comprising means for monitoring the operation of said pump means, said monitoring means being operably coupled to said telemetry means.

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122. A programmable infusion system in accordance with claim 121, wherein said monitoring means comprises pressure sensing means disposed in the path of flow of said selected medication into said living body, said pressure sensing means providing a signal in response to a pressure pulse in said path of flow.

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123. A programmable infusion system in accordance with claim 122, further comprising first means for indicating the operation of said pump means when a decrease in volume of said variable volume means is not followed by a signal from said monitoring means corresponding to a pressure pulse of said selected medication expelled into said outlet chamber, said first indicating means being operably coupled to said telemetry means.

parallel claim 19

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39 124

124. A programmable infusion system in accordance with claim 123, further comprising second means for indicating the operation of said pump means when a signal is provided by said monitoring means absent a decrease in volume of said variable volume means ~~caused by said moving means~~, said second indicating means being operably coupled to said telemetry means.

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1 125

125. A programmable infusion system in accordance with claim 124, wherein one of said ^{at least one} remotely commandable operational ~~characteristics~~ ^{characteristic} comprises an infusion rate variable on command, said infusion apparatus further comprising means for inhibiting said infusion means from infusing said selected medication if a preselected medication infusion rate is exceeded by a commanded infusion rate, said inhibiting means being operably coupled to said infusion means.

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126. A programmable infusion system in accordance with claim 125, wherein said inhibiting means comprises at least one means for defining a fixed infusion rate limit.

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127. A programmable infusion system in accordance with claim 126, wherein said ^{at least one} means for defining a fixed infusion rate limit is hardwired.

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128. A programmable infusion system in accordance with claim 127, wherein said preselected medication infusion rate is remotely selectable.

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41 129

129. A programmable infusion system in accordance with claim 128, wherein said preselected medication infusion rate comprises a remotely selectable rate and a fixed rate, said remotely selectable rate being limited by said fixed rate.

CLAIM 46
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Sub 84

130. A programmable infusion system in accordance with claim 129, wherein said inhibiting means comprises:

at least one programmable rate memory unit coupled to said command receiver means, each of said programmable rate memory units for receiving and storing an infusion rate input command corresponding to said remotely selectable rate;

at least one limit control unit each of which provides a fixed rate limit; and

means for comparing each of said infusion rate input commands to a corresponding said fixed rate limit, infusion of said medication at a rate exceeding said fixed rate limit being inhibited.

47
D'E 46 131. A programmable infusion system in accordance with claim 130, further comprising command decoder means for coupling ^{each of} said ^{units} at least one ~~said~~ programmable rate memory ^{unit} to said command receiver means, said command decoder means for decoding said command signals received by said command receiver means into ^{corresponding} said infusion rate inputs for receipt by and storage ⁱⁿ said at least one programmable rate memory ^{units} ~~unit~~.

48
E 46 132. A programmable infusion system in accordance with claim 130, wherein ^{at least one} each of said limit control units ^{is} ~~are~~ hardwired.

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46 133. A programmable infusion system in accordance with claim 130, further comprising means for generating an alarm signal when any infusion rate input command exceeds a corresponding fixed rate limit.

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46 134. A programmable infusion system in accordance with claim 130, wherein said inhibiting means precludes infusion of said medication by said infusion means when the selected said

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commandable infusion rate exceeds said preselected medication
infusion rate during a ~~fixed~~ ^{of a predetermined length} window of time which shifts
continuously.

41 51
125. A programmable infusion system in accordance with claim
125, wherein said inhibiting means precludes infusion of said
medication by said infusion means when the selected said
commandable infusion rate ^{preselected medication} exceeds said ~~preselected~~ infusion rate
during a ~~fixed~~ ^{of a predetermined length} window of time which shifts continuously.

CLAIMS
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136. A programmable infusion system in accordance with claim
125, wherein said infusion means includes a pump means which
executes in pulses, said inhibiting means comprising a
programmable memory rate unit coupled to said command receiver
for storing initially a ^{local limit} number corresponding to a first maximum
number of infusion pulses preselected as allowable during a
first shifting time window of a predetermined length, pulse
quantities being subtracted from said number stored in said
programmable memory rate unit as infusion pulses are executed by
said infusion means, ^E pulse quantities being added to said stored
number as time elapses such that said number does not exceed
said first maximum number, said subtraction and addition being
accomplished in running integral fashion, said inhibiting means
not permitting pulsing of said pump means a number of times in
excess of said number stored in said programmable memory rate
unit.

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52-
137. A programmable infusion system in accordance with claim
136, wherein said memory rate unit also records the number of
pulses which have been inhibited and causes said pump means of
said infusion means to execute said pulses when said pulses can
be subtracted from said number stored in said programmable
memory rate unit as a result of the elapse of time.

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138. A programmable infusion system in accordance with claim 136, wherein said programmable memory rate unit also stores initially another ^{dose limit} number corresponding to a second maximum number of infusion pulses preselected as allowable during a second shifting time window of a predetermined length, said second shifting time window being longer in length than said first shifting time window, pulse quantities being subtracted from said another ^{dose limit} number stored in said programmable memory rate unit as infusion pulses are executed by said infusion means, pulse quantities being added to said another ^{dose limit} stored number as time elapses such that said another ^{dose limit} number does not exceed said first maximum number, said subtraction and addition being accomplished in running integral fashion, said inhibiting means not permitting pulsing of said pump means ^{+ a dose} a number of times in excess of said another ^{dose limit} number stored in said programmable memory rate unit.

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⁵⁵
~~54~~ 139. A programmable infusion system in accordance with claim 138, wherein said rate memory unit also records the number of pulses which have been inhibited and causes said pump means of said infusion means to execute said pulses when said pulses can be subtracted from said ^{both dose limit} numbers stored in said programmable memory rate unit.

⁵⁶
~~55~~ 140. A programmable infusion system in accordance with claim 139, wherein said inhibiting means further comprises at least one fixed infusion rate limit which limits the total maximum infusion rate of said infusion means.

⁵⁷
~~56~~ 141. A programmable infusion system in accordance with claim 140, wherein said fixed infusion rate limit is hardwired.

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⁵⁸
~~142~~. A programmable infusion system in accordance with claim
⁵⁴
~~138~~, further comprising means for generating an alarm signal
when any commanded infusion rate results in the inhibiting of
pulsing of said pump means by said inhibiting means.

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⁵⁸
~~142~~. A programmable infusion system in accordance with claim
~~142~~, wherein said alarm signal comprises a subcutaneous
electrical stimulation.

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⁵⁴
~~138~~. A programmable infusion system in accordance with claim
~~138~~, further comprising command decoder means for coupling said
command receiver means to said programmable memory rate unit,
said command decoder means for decoding said command signals
received by said command receiver means into said first and
^{maximum}
second numbers of infusion pulses.

⁶¹
⁴¹
~~125~~. A programmable infusion system in accordance with claim
~~125~~, wherein said inhibiting means is operably coupled to said
telemetry means, said inhibiting means providing a signal to
said telemetry means for telemetering to said telemetry
receiving means operational information pertaining to the
functions of said inhibiting means.

⁶²
⁴¹
~~125~~. A programmable infusion system in accordance with claim
~~125~~, further comprising means for generating an alarm signal
when said inhibiting means inhibits said infusion means.

⁶³
⁴¹
~~125~~. A programmable infusion system in accordance with claim
~~125~~, further comprising means for recording when said inhibiting
means inhibits said infusion means.

⁶⁴
⁶³
~~147~~. A programmable infusion system in accordance with claim
~~147~~, wherein said recording means is coupled to said telemetry

means, said recording means providing a signal to said telemetry means for telemetering to said telemetry receiving means operational information pertaining to said inhibiting means as recorded by said recording means.

65
149. A programmable infusion system in accordance with claim 85, said infusion apparatus further comprising means for generating a distinctive alarm signal pattern for each of a plurality of improper ^{operational} operation conditions.

Sub E6
CLAIMS 66-78 ON
FELLOW
174-175
150. A programmable infusion system in accordance with claim 149, wherein said alarm signal is delivered to said living body subcutaneously.

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11 2 12
151. A programmable infusion system in accordance with claim 150, further comprising means for detecting a medication leak, coupled to said alarm means, wherein one of said improper operation conditions comprises a medication leak out of said medication reservoir.

152. A programmable infusion system in accordance with claim 150, further comprising means for detecting a body fluid leak, coupled to said alarm means, wherein one of said improper operation conditions comprises a leak of body fluids into said infusion apparatus.

153. A programmable infusion system in accordance with claim 150, further comprising means for detecting the rate at which said infusion means is operating, coupled to said alarm means, wherein one of said improper operation conditions comprises operation of said infusion means at an improper rate.

154. A programmable infusion system in accordance with claim 150, wherein one of said improper operation conditions comprises receiving of a command by said command receiver which cannot be executed.

155. A programmable infusion system in accordance with claim 150, further comprising battery means for powering said infusion means and means for determining the voltage of said battery coupled to said alarm means, wherein one of said improper operation conditions comprises low battery voltage.

156. A programmable infusion system in accordance with claim 150, further comprising means for detecting the amount of medication disposed in said reservoir coupled to said alarm means, wherein one of said improper operation conditions comprises a preselected amount of medication remaining in said medication reservoir.

157. A programmable infusion system in accordance with claim 149, further comprising means for detecting a medication leak, coupled to said alarm means, wherein one of said improper operation conditions comprises a medication leak out of said medication reservoir.

158. A programmable infusion system in accordance with claim 149, further comprising means for detecting a body fluid leak, coupled to said alarm means, wherein one of said improper operation conditions comprises a leak of body fluids into said infusion apparatus.

159. A programmable infusion system in accordance with claim 149, further comprising means for detecting the rate at which said infusion means is operating coupled to said alarm means,

wherein one of said improper operation conditions comprises operation of said infusion means at an improper rate.

160. A programmable infusion system in accordance with claim 149, wherein one of said improper operation conditions comprises receiving of a command by said command receiver which cannot be executed.

161. A programmable infusion system in accordance with claim 149, further comprising battery means for powering said infusion means and means for determining the voltage of said battery, coupled to said alarm means wherein one of said improper operation conditions comprises low battery voltage.

162. A programmable infusion system in accordance with claim 149, further comprising means for detecting the amount of medication disposed in said reservoir coupled to said alarm means, wherein one of said improper operation conditions comprises a preselected amount of medication remaining in said medication reservoir.

163. A programmable infusion system in accordance with claim 149, further comprising means for simulating said improper operational conditions for test purposes.

164. A programmable infusion system in accordance with claim 85, wherein said infusion means includes means for pumping a preselected amount of medication into said living body, said infusion apparatus further comprising means for recording the rate at which pumping is effected by said pumping means.

165. A programmable infusion system in accordance with claim 164, wherein said recording means comprises:

means for storing the rate at which said ~~pumping~~ means pumps over a preselected time period;

means for storing a programmable input corresponding to a minimum medication infusion rate; and

means for comparing the rate recorded by said recording means to the rate stored in said ~~storing~~ means.

166. A programmable infusion system in accordance with claim 165, further comprising means for providing an alarm signal when said rate recorded by said recording means is less than said minimum medication infusion rate.

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81 ~~167~~. A programmable infusion system in accordance with claim ~~165~~, wherein said recording means is coupled to said telemetry means for telemetering information ~~deduced~~ ^{recorded} by said recording means out of said living body.

84
80 ~~168~~. A programmable infusion system in accordance with claim ~~164~~, wherein said recording means comprises:

P₁ means for storing the rate at which said ~~pumping~~ ^{pump} means pumps over a preselected time period; and

P₂ means for storing the rate at which said ~~pumping~~ ^{pump} means is signalled to pump over said preselected time period.

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84 ~~169~~. A programmable infusion system in accordance with claim ~~166~~, further comprising means for comparing the rates recorded by both said storing means.

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85 ~~170~~. A programmable infusion system in accordance with claim ~~169~~, wherein said comparing means is coupled to said telemetry means for telemetering information ~~deduced~~ ^{outputted} by said comparing means out of said living body.

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85 171. A programmable infusion system in accordance with claim
169, further comprising means for providing an alarm signal when
the rate at which said ^{pump} ~~pumping~~ means pumps is different than the
rate at which said ^{pump 1} ~~pumping~~ means ^{is} ~~if~~ signalled to pump.

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84 172. A programmable infusion system in accordance with claim
168, wherein said recording means is coupled to said telemetry
means for telemetering information recorded by ~~both~~ said
recording means out of said living body.

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80 173. A programmable infusion system in accordance with claim
164, wherein said pump means executes in pulses, said recording
means comprising a pulse rate detector comprising:

P₁ means for counting the number of times said ~~pumping~~ means
pumps over a preselected time period, said counting means
storing the count;

P₁ minimum rate memory means for storing a programmable number
input corresponding to a minimum medication infusion rate; and

P₁ means for comparing the number counted by said counting
means with said programmable number input stored in said minimum
rate memory means.

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89 174. A programmable infusion system in accordance with claim
173, further comprising means for providing an alarm signal when
said count is less than said programmable number input stored in
said minimum rate memory means.

91
90 175. A programmable infusion system in accordance with claim
174, wherein said alarm signal comprises a subcutaneous
electrical stimulation.

92
90 176. A programmable infusion system in accordance with claim
174, wherein said counting means comprises a pressure
transducer.

93
87 177. A programmable infusion system in accordance with claim
173, wherein said comparing means is coupled to said telemetry
E 112 means for telemetering information ^{outputted} ~~deduced~~ by said comparing
means out of said living body.

94
80 178. A programmable infusion system in accordance with claim
164, wherein said pump means executes in pulses, said recording
means comprising a pulse recorder comprising:

E P₁ means for counting the number of times said ^{pump} ~~pumping~~ means
pumps over a preselected time period, said counting means
storing the count; and

E P₁ means for counting the number of times said ^{pump} ~~pumping~~ means is
commanded to pump over said preselected time period.

D1 95
94 179. A programmable infusion system in accordance with claim
E 112 178, wherein said pulse recorder further comprises means for
comparing the ^{numbers} ~~number~~ recorded by both said counting means.

96
95 180. A programmable infusion system in accordance with claim
E 112 179, wherein said comparing means is coupled to said telemetry
means for telemetering information ^{outputted} ~~deduced~~ by said comparing
means out of said living body.

97
94 181. A programmable infusion system in accordance with claim
178, further comprising means for providing an alarm signal when
said numbers recorded by both said counting means are different.

98
92 182. A programmable infusion system in accordance with claim
181, wherein said alarm signal comprises a subcutaneous
electrical stimulation.

⁹⁹
~~94~~ ¹⁸³ 183. A programmable infusion system in accordance with claim
~~178~~, wherein said recording means is coupled to said telemetry
means for telemetering information recorded by both said
counting means out of said living body.

¹⁸⁶
~~94~~ ¹⁸⁴ 184. A programmable infusion system in accordance with claim
~~178~~, wherein said first recited counting means comprises a
pressure transducer.

E ¹⁰¹
1 ¹⁸⁵ 185. A programmable infusion system in accordance with claim
~~85~~, further comprising means for maintaining the pressure within
said medication reservoir at a pressure level below the internal
pressure of said living body.

D' ¹⁰²
¹⁰¹ ¹⁸⁶ 186. A programmable infusion sytem in accordance with claim
~~185~~, wherein said pressure maintaining means comprises:
R a flexible diaphragm which divides said medication reservoir
into a medication chamber and a liquid-vapor pool chamber; and
R a liquid vapor pool disposed within said liquid-vapor pool
chamber, the proportion of liquid to vapor in said liquid-vapor
pool varying in response to variations in the amount of said
selected medication disposed in said medication chamber.

¹⁰³
¹⁰² ¹⁸⁷ 187. A programmable infusion system in accordance with claim
~~186~~, said infusion apparatus further comprising switch means
disposed within said medication reservoir, said switch means
being coupled to said telemetry means and being activated when
said flexible diaphragm is disposed in a preselected
relationship relative to said switch means, said telemetry means
telemetering a signal indicative of such an operational
condition to said telemetry receiving means.

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104
E 103 ~~188~~. A programmable infusion system in accordance with claim
~~187~~, wherein said switch means is activated by pressure exerted
thereon by said flexible diaphragm, said pressure being less
than the ambient pressure of said body.

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102 ~~189~~. A programmable infusion system in accordance with claim
~~188~~, said infusion apparatus further comprising an antechamber
through which access is gained to said medication reservoir, and
a reservoir inlet valve located between said antechamber and
said medication chamber, said reservoir inlet valve being
operable ~~and~~ when the pressure in said antechamber exceeds the
pressure in ^{said medication} ~~the reservoir~~ chamber by more than a predetermined
differential.

D' 106
E 105 ~~190~~. A programmable infusion system in accordance with claim
~~189~~, wherein the volume of said antechamber is less than 10% the
volume of said ^{medication} ~~reservoir~~ chamber.

107
105 ~~191~~. A programmable infusion system in accordance with claim
~~189~~, further comprising an inlet filter means operably disposed
between said antechamber and said medication chamber for
preventing impurities in said selected medication in said
antechamber from passing into said medication chamber when said
reservoir inlet valve is opened, said filter means also
preventing said selected medication in said medication chamber
from rapidly entering said living body in the event of a leak in
said inlet valve.

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105 ~~192~~. A programmable infusion system in accordance with claim
~~189~~, further comprising means for programmed pumping of
fixed-volume pulses of medication into said living body.

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109
193. A programmable infusion system in accordance with claim 93, further comprising means for injecting medication into said medication reservoir, said injecting means being coupled to said telemetering receiver means, and programming means coupled to said ^{telemetry} ~~telemetering~~ means for indicating when ejection of medication into said medication reservoir is appropriate.

110
194. A programmable infusion system for providing medication to a living body ^{of a patient} comprising;

P₁ an infusion apparatus for implantation in said living body, said apparatus including

P₂ a medication reservoir for storing selected medication,
P₂ means for infusion said selected medication stored in said medication reservoir into said living body, said infusion means having at least one remotely commandable operational characteristic and being powered by an implanted power source,

P₂ command receiver means coupled to said infusion means for receiving command signals, said command receiver means being powered by a power source external to said living body, and

P₂ means for telemetering operational information pertaining to said infusion apparatus out of said living body;

K command source means external to said living body for transmitting said command signals to be received by said command receiver means;

P₁ means for receiving said telemetered operational information external to said living body; and

P₁ means for selectively supplying power to said command receiver means, said supply means being coupled to said external power source, said supply means being external to said living body.

¹¹¹
~~118~~ 193. A programmable infusion system in accordance with claim
~~194~~, wherein said supply means provides an alternating field.

¹¹²
~~111~~ 196. A programmable infusion system in accordance with claim
~~195~~, wherein said infusion apparatus further comprises detector
means for detecting said alternating field and for converting
the same into electrical energy, said detecting means being
coupled to said command receiver.

¹¹³
~~112~~ 197. A programmable infusion system in accordance with claim
~~196~~, wherein said infusion apparatus further comprises means for
rectifying said electrical energy into a d.c. power signal.

¹¹⁴
~~113~~ 198. A programmable infusion system in accordance with claim
~~197~~, wherein said d.c. power signal is coupled to said implanted
power source to effect the charging thereof.

¹¹⁵
~~113~~ 199. A programmable infusion system in accordance with claim
~~198~~, wherein said telemetry means is coupled to said rectifier
means and is powered by said d.c. power signal.

¹¹⁶
~~110~~ 200. A programmable infusion system in accordance with claim
~~199~~, wherein said ^{telemetry} ~~telemetry~~ means is also supplied power by
said supply means.

¹¹⁷
~~110~~ 201. A programmable infusion system in accordance with claim
~~194~~ further comprising means for selectively recharging said
implanted power source, said recharging means being powered by
said supply means.

¹¹⁸
~~110~~ 202. A programmable infusion system in accordance with claim
~~194~~, wherein one of said command signals transmitted by said
command source means comprises a signal which corresponds to a

selected operational rate at which said infusion means will infuse said selected medication into said living body.

¹¹⁹
~~110~~ 203. A programmable infusion system in accordance with claim ~~194~~, wherein said command source and said telemetry receiving means are embodied in a patient programming unit external to said living body, said patient programming unit having a plurality of operational medication dose inputs each corresponding to a medication infusion rate selectable and requestable by the patient, said patient programming unit for selectively transmitting a command signal corresponding to a selected said medication dose ^{one of} ~~input~~ ^{inputs} ~~input~~.

¹²⁰
~~119~~ 204. A programmable infusion system in accordance with claim ~~203~~, wherein said infusion apparatus further comprises electronic control means coupled to said infusion means and said command receiver means, said electronic control means ^{including means} for maintaining a history of the infusion rate at which said infusion means has operated, said electronic control means ^{including means} for precluding the infusion of said selected medication of said infusion means if said rate requested by said patient programming unit exceeds a predetermined safe medication infusion rate based on said maintained history.

¹²¹
~~120~~ 205. A programmable infusion system in accordance with claim ~~204~~, wherein said electronic control means is coupled to said telemetry means, said patient programming unit including means for indicating to said patient if said selected infusion rate exceeds said predetermined safe medication infusion rate, said ^{electronic} ~~selective~~ control means selectively sending a signal to said indicating means via said telemetry means and said telemetry receiving means, said telemetry receiving means being coupled to said indicating means.

119-122
206. A programmable infusion system in accordance with claim
205, wherein said patient programming unit further comprises
annunciator means and visual display means for providing
information regarding previously selected medication infusion
rates, for indicating whether a proper programming of a
presently requested infusion rate has been communicated to said
command receiver, and for selectively providing information as
to the time and rate of previously selected medication infusion.

123
170-207. A programmable infusion system in accordance with claim
194, wherein said infusion means comprises a fluid handling
mechanism for delivering said selected medication, said
operational information including information about the
operation of said fluid handling mechanism.

01 124
123-208. A programmable infusion system in accordance with claim
207, wherein said fluid handling mechanism comprises means for
pumping said selected medication.

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increase in volume of said variable volume means permitting drawing of said selected medication into said pump means, a decrease in volume of said variable volume means permitting expulsion of said selected medication from said pump means.

Sub E9

213. A programmable infusion system in accordance with claim 212, wherein said variable volume means comprises at least one flexible wall, movement of said ^{at least one} flexible wall varying the value of said variable volume means, and means for moving said ^{at least one} flexible wall.

214. A programmable infusion system in accordance with claim 213, further comprising spring means for urging said ^{at least one} wall in a manner which decreases the volume of said variable volume means, the magnitude of the force applied to and stored by said spring means increasing as the volume of said variable volume means increases due to the displacement of said ^{at least one} flexible wall thereof by said moving means.

215. A programmable infusion system in accordance with claim 214, wherein said flexible wall comprises a bellows assembly having mounted on one end thereof a plate, the other end of said bellows being in communication with said selected medication, the walls of said bellows serving as said spring means.

¹³¹
~~215~~ 216. A programmable infusion system in accordance with claim ¹³⁷ 215, wherein said plate has a surface in contact with a said selected medication when drawn into said variable volume means. ✓

¹³³
¹³⁶ 217. A programmable infusion system in accordance with claim ¹³⁶ 216, wherein said bellows ^{assembly} is inhibited from moving said plate when the pressure (p) in said ^{variable} volume means exceeds the spring force (F) of said bellows ^{assembly} divided by the wetted area (A)

ϵ of said surface of said plate in ^{contact} with said selected medication, that is when $p > \frac{F}{A}$.

NK Sub 610
NP 218. A programmable infusion system in accordance with claim 215, wherein said moving means comprises said plate being magnetizable and a coil disposed proximate to said plate, said coil selectively radiating a pulsing magnetic field, pulsing of said coil causing said plate to be moved.

135
134 219. A programmable infusion system in accordance with claim 218, wherein said plate comprises a permanent magnet.

136
131 220. A programmable infusion system in accordance with claim 215, further comprising means for limiting the distance said plate can move in both ^{the} volume increasing direction and ^{the} volume decreasing direction.

D1 137
128 221. A programmable infusion system in accordance with claim 212, wherein said infusion means further comprises:

P an interface pressure valve through which said selected medication enters said variable volume means from said medication reservoir, said interface pressure valve being normally closed;

222 P an outlet chamber which is in communication with said living body; and

ϵ P an outlet pressure valve located between said variable volume means and said outlet chamber, said outlet pressure ^{valve} ~~value~~ being normally closed, an increase in volume of said variable volume means causing said interface pressure valve to open and medication to enter said variable volume means, a decrease in volume of said variable volume means causing said outlet pressure ^{valve} ~~value~~ to open and said interface pressure valve to

close, so as to permit medication to enter said outlet chamber as a pressure pulse.

¹³⁸
~~137~~ 222. A programmable infusion system in accordance with claim ~~221~~, wherein said outlet chamber comprises an elastic wall having a fluidic capacitive effect on the flow of said selected medication and a filter element through which liquid flow to the said living body is resisted, said elastic wall and said filter comprising a fluid resistance-capacitance arrangement with respect to said flow of said selected medication from said outlet chamber into said living body.

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¹³⁹
~~137~~ 223. A programmable infusion system in accordance with claim ~~211~~, further comprising means for feeding said selected medication into said living body from said pump means in a flow which decays exponentially over time.

¹⁴⁰
~~139~~ 224. A programmable infusion system in accordance with claim ~~223~~, wherein said feeding means comprises a mechanical resistance (R) and a mechanical capacitance (C) circuit resulting in an exponentially decaying outflow of medication for each said fixed volume pulse.

¹⁴¹
~~139~~ 225. A programmable infusion system in accordance with claim ~~208~~, wherein said infusion means further comprises an outlet chamber which is in communication with said living body, said pump means expelling said selected medication into said outlet chamber, ~~means~~ and means for monitoring the operation of said pump means, said monitoring means being disposed in said outlet chamber and providing a signal in response to a pressure pulse in said outlet chamber caused by said pump means, said monitoring means being operably coupled to said telemetry means.

142
226. A programmable infusion system in accordance with claim
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225, wherein said monitoring means comprises a pressure
transducer.

143
227. A programmable infusion system in accordance with claim
147
225, further comprising first means for indicating the operation
of said pump means when a decrease in volume of said variable
volume means is not followed by a signal from said monitoring
means corresponding to a pressure pulse of said selected
medication expelled into said outlet chamber, said first
indicating means being operably coupled to said telemetry means.

144
228. A programmable infusion system in accordance with claim
143
227, further comprising second means for indicating the
operation of said pump means when a signal is provided by said
monitoring means absent a decrease in volume of said variable
volume means ~~caused by said moving means~~, said second indicating
means being operably coupled to said telemetry means.

145
229. A programmable infusion system in accordance with claim
124
208, further comprising means for monitoring the operation of
said pump means, said monitoring means being operably coupled to
said telemetry means.

146
230. A programmable infusion system in accordance with claim
145
229, wherein said monitoring means comprises pressure sensing
means disposed in the path of flow of said selected ^{medication} medication
into said ^{living} living body, said pressure sensing means providing a
signal in response to a pressure pulse in said path of flow.

CLAIM 811
147 on
231. A programmable infusion system in accordance with claim
230, further comprising first means for indicating the operation
of said pump means when a decrease in volume of said variable

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NP

volume means is not followed by a signal from said monitoring means corresponding to a pressure pulse of said selected medication expelled into said outlet chamber, said first indicating means being operably coupled to said telemetry means.

148

232. A programmable infusion system in accordance with claim 231, further comprising second means for indicating the operation of said pump means when a signal is provided by said monitoring means absent a decrease in volume of said variable volume means ~~caused by said moving means~~, said second indicating means being operably coupled to said telemetry means.

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E

148 233. A programmable infusion system in accordance with claim 194, wherein one of said ^{at least one} remotely commandable operational characteristics comprises an infusion rate variable on command, said infusion apparatus further comprising means for inhibiting said infusion means from infusing said selected medication if a preselected medication infusion rate is exceeded by a commanded infusion rate, said inhibiting means being operably coupled to said infusion means.

E

D1

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234. A programmable infusion system in accordance with claim 233, wherein said inhibiting means comprises at least one means for defining a fixed infusion rate limit.

151

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150 235. A programmable infusion system in accordance with claim 234, wherein said ^{at least one} means for defining a fixed infusion rate limit is hardwired.

152

236. A programmable infusion system in accordance with claim 235, wherein said preselected medication infusion rate is remotely selectable.

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153
237. A programmable infusion system in accordance with claim
145
233, wherein said preselected medication infusion rate comprises
a remotely selectable rate and a fixed rate, said remotely
selectable rate being limited by said fixed rate.

CUA 152
154 - 238. A programmable infusion system in accordance with claim
157 237, wherein said inhibiting means comprises:

at least one programmable rate memory unit coupled to said
command receiver means, each of said programmable rate memory
units for receiving and storing an infusion rate input command
corresponding to said remotely selectable rate;

at least one limit control unit each of which provides a
fixed rate limit; and

means for comparing each of said infusion rate input
commands to a corresponding said fixed rate limit, infusion of
said medication at a rate exceeding said fixed rate limit being
inhibited.

239. A programmable infusion system in accordance with claim
238, further comprising command decoder means for coupling said
at least one said programmable rate memory limit to said command
receiver means, said command decoder means for decoding said
command signals received by said command receiver means into
said infusion rate inputs for receipt by and storage in said at
least one programmable rate memory unit.

240. A programmable infusion system in accordance with claim
154 238, wherein each of said limit control units ^{at least one} ~~is~~ ^{is} ~~are~~ hardwired.

157
154 241. A programmable infusion system in accordance with claim
239, further comprising means for generating an alarm signal
when any infusion rate input command exceeds a corresponding
fixed rate limit.

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157 158
242. A programmable infusion system in accordance with claim
238, wherein said alarm signal comprises a subcutaneous
electrical stimulation.

159
243. A programmable infusion system in accordance with claim
238, wherein said inhibiting means precludes infusion of said
medication by said infusion means when the selected said
commandable infusion rate exceeds said preselected medication
infusion rate during a ~~fixed~~ ^{of a predetermined length} window of time which shifts
continuously.

160
244. A programmable infusion system in accordance with claim
233, wherein said inhibiting means precludes infusion of said
medication ^{by} said infusion means when the selected said
commandable infusion rate exceeds said preselected medication
infusion rate during a ~~fixed~~ ^{of a predetermined length} window of time which shifts
continuously.

CLAIM 8132
161-164 on
161/10W
245. A programmable infusion system in accordance with claim
233, wherein said infusion means includes a pump means which
executes in pulses, said inhibiting means comprising a
programmable memory rate unit coupled to said command receiver
for storing initially a ^{first value} number corresponding to a first maximum
number of infusion pulses preselected as allowable during a
first shifting time window of a predetermined length, pulse
quantities being subtracted from said number stored in said
programmable memory rate unit as infusion pulses are executed by
said infusion means, pulse quantities being added to said stored
number as time elapses such that said number does not exceed
said first maximum number, said subtraction and addition being
accomplished in running integral fashion, said inhibiting means
not permitting pulsing of said pump means ^{at a rate} a number of times in
excess of said number stored in said programmable memory rate
unit.

246. A programmable infusion system in accordance with claim 245, wherein said memory rate unit also records the number of pulses which have been inhibited and causes said pump means of said infusion means to execute said pulses when said pulses can be subtracted from said ^{first limit} number stored in said programmable memory rate unit as a result of the elapse of time.

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247. A programmable infusion system in accordance with claim 245, wherein said programmable memory rate unit also stores initially another ^{second limit} number corresponding to a second maximum number of infusion pulses preselected as allowable during a second shifting time window of a predetermined length, said second shifting time window being longer in length than said first shifting time window, pulse quantities being subtracted in ~~fixed running integral~~ fashion from said another number stored in said programmable memory rate unit as infusion pulses are executed by said infusion means, pulse quantities being added to said second number as time elapses such that said another ^{second limit} number does not exceed said first maximum number, said subtraction and addition being accomplished in running integral fashion, said inhibiting means not permitting pulsing of said pump means at a ^{rate} ~~number~~ of times in excess of said another number stored in said programmable memory rate unit.

248. A programmable infusion system in accordance with claim 247, wherein said rate memory unit also records the number of pulses which have been inhibited and causes said infusion means to execute said pulses when said pulses can be subtracted from said ^{unit} numbers stored in said programmable memory rate unit.

165
249. A programmable infusion system in accordance with claim 248, wherein said inhibiting means further comprises at least one fixed infusion rate limit which limits the total maximum infusion rate of said infusion means.

¹⁶⁶
~~165~~ 250. A programmable infusion system in accordance with claim
~~249~~, wherein said fixed infusion rate limit is hardwired.

¹⁶⁷
~~163~~ 251. A programmable infusion system in accordance with claim
~~247~~, further comprising means for generating an alarm signal
when any commanded infusion rate results in the inhibiting of
pulsing of said pump means by said inhibiting means.

¹⁶⁸
~~167~~ 252. A programmable infusion system in accordance with claim
~~251~~, wherein said alarm signal comprises a subcutaneous
electrical stimulation.

¹⁶⁹
~~165~~ 253. A programmable infusion system in accordance with claim
~~247~~, further comprising command decoder means for coupling said
command receiver means to said programmable memory rate unit,
said command decoder means for decoding said command signals
received by said command receiver means into said first and
^{maximum}
second numbers of infusion pulses.

¹⁷⁰
~~149~~ 254. A programmable infusion system in accordance with claim
~~233~~, wherein said inhibiting means is operably coupled to said
telemetry means, said inhibiting means providing a signal to
said telemetry means for telemetering to said telemetry
receiving means operational information pertaining to the
functions of said inhibiting means.

¹⁷¹
~~149~~ 255. A programmable infusion system in accordance with claim
~~233~~, further comprising means for generating an alarm signal
when said inhibiting means inhibits said infusion means.

¹⁷²
~~149~~ 256. A programmable infusion system in accordance with claim
~~233~~, further comprising means for recording when said inhibiting
means inhibits said infusion means.

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257. A programmable infusion system in accordance with claim 233, wherein said recording means is coupled to said telemetry means, said recording means providing a signal to said telemetry means for telemetering to said telemetry receiving means operational information pertaining to said inhibiting means as recorded by said recording means.

144
258. A programmable infusion system in accordance with claim 194, said infusion apparatus further comprising means for generating a distinctive alarm signal pattern for each of a plurality of improper ^{operational} ~~operation~~ conditions.

Sub E
CLAIMS
175-187
D 1 on
YELLOW
259. A programmable infusion system in accordance with claim 258, wherein said alarm signal is delivered to said living body subcutaneously.

260. A programmable infusion system in accordance with claim 259, further comprising means for detecting a medication leak, coupled to said alarm ^{means}, wherein one of said improper operation conditions comprises a medication leak out of said medication reservoir.

261. A programmable infusion system in accordance with claim 259, further comprising means for detecting a body fluid leak, coupled to said alarm means wherein one of said improper operation conditions comprises a leak of body fluids into said infusion apparatus.

262. A programmable infusion system in accordance with claim 259, further comprising means for detecting the rate at which said infusion means is operating coupled to said alarm means, wherein one of said improper operation conditions comprises operation of said infusion means at an improper rate.

263. A programmable infusion system in accordance with claim 259, wherein one of said improper operation conditions comprises receiving of a command by said command receiver, which cannot be executed.

11/2/86
(see claim 14)
264. A programmable infusion system in accordance with claim 259, further comprising battery means for powering said infusion means and means for determining the voltage of said battery, coupled to said alarm, means wherein one of said improper operation conditions comprises low battery voltage.

11/2/86
(see claim 14)
D 1
265. A programmable infusion system in accordance with claim 259, further comprising means for detecting the amount of medication disposed in said reservoir, coupled to said alarm means, wherein one of said improper operation conditions comprises a preselected amount of medication remaining in said medication reservoir.

11/2/86
266. A programmable infusion system in accordance with claim 258, further comprising means for detecting a medication leak, coupled to said alarm means, wherein one of said improper operation conditions comprises a medication leak out of said medication reservoir.

11/2/86
267. A programmable infusion system in accordance with claim 258, further comprising means for detecting a body fluid leak, coupled to said alarm means, wherein one of said improper operation conditions comprises a leak of body fluids into said infusion apparatus.

11/2/86
268. A programmable infusion system in accordance with claim 258, further comprising means for detecting the rate at which said infusion means is operating, coupled to said alarm means,

wherein one of said improper operation conditions comprises operation of said infusion means at an improper rate.

269. A programmable infusion system in accordance with claim 258, wherein one of said improper operation conditions comprises receiving of a command by said command receiver which cannot be executed.

270. A programmable infusion system in accordance with claim 258, further comprising battery means for powering said infusion means and means for determining the voltage of said battery means coupled to said alarm means wherein one of said improper operation condition comprises low battery voltage.

271. A programmable infusion system in accordance with claim 258, further comprising means for detecting the amount of medication disposed in said reservoir coupled to said alarm means, wherein one of said improper operation conditions comprises a preselected amount of medication remaining in said medication reservoir.

188
174 272. A programmable infusion system in accordance with claim 258, further comprising means for simulating said improper operational conditions for test purposes.

189
110 273. A programmable infusion system in accordance with claim 258, wherein said infusion means includes means for pumping a preselected amount of medication into said living body, said infusion apparatus further comprising means for recording the rate at which pumping is effected by said pump means.

CLAIMS
170-171
E 15
YELLOW
89
274. A programmable infusion system in accordance with claim 273, wherein said recording means comprises:

means for storing the rate at which said ~~pumping~~ means pumps over a preselected time period;

means for storing a programmable input corresponding to a minimum medication infusion rate; and

means for comparing the rate recorded by said recording means to the rate stored in said storing means.

275. A programmable infusion system in accordance with claim 274, further comprising means for providing an alarm signal when said rate recorded by said ~~recording~~ means is less than said minimum medication infusion rate.

191 276. A programmable infusion system in accordance with claim 274, wherein said recording means is coupled to said telemetry means for telemetering information ~~deduced~~ ^{recorded} by said recording means out of said living body.

189 193 277. A programmable infusion system in accordance with claim 275, wherein said recording means comprises:

P₁ means for storing the rate at which said ~~pumping~~ means pumps over a preselected time period; and

P₁ means for storing the rate at which said ~~pumping~~ means is signalled to pump over said preselected time period.

194 193 278. A programmable infusion system in accordance with claim 277, further comprising means for comparing the rates recorded by both said storing means.

195 194 279. A programmable infusion system in accordance with claim 278, wherein said comparing means is coupled to said telemetry means for telemetering information ~~deduced~~ ^{outputted} by said comparing means out of said living body.

196
194 280. A programmable infusion system in accordance with claim
278, further comprising means for providing an alarm signal when
the rate at which said ^{pump} ~~pumping~~ means pumps is different than the
rate at which said ^{pump} ~~pumping~~ means ^{is} ~~is~~ signalled to pump.

197
193 281. A programmable infusion system in accordance with claim
277, wherein said recording means is coupled to said telemetry
means for telemetering information recorded by ~~both~~ said
recording means out of said living body.

198
189 282. A programmable infusion system in accordance with claim
273, wherein said pump means executes in pulses, said recording
means comprising a pulse rate detector comprising:
P₁ means for counting the number of times said ~~pumping~~ means
pumps over a preselected time period, said counting means
storing the count;
P₂ minimum rate memory means for storing a programmable number
input corresponding to a minimum medication infusion rate; and
P₃ means for comparing the number counted by said counting
means with said programmable number input stored in said minimum
rate memory means.

199
188 283. A programmable infusion system in accordance with claim
282, further comprising means for providing an alarm signal when
said count is less than said programmable number input stored in
said minimum rate memory means.

200
187 284. A programmable infusion system in accordance with claim
283, wherein said alarm signal comprises a subcutaneous
electrical stimulation.

201
186 285. A programmable infusion system in accordance with claim
283, wherein said counting means comprises a pressure
transducer.

²⁰²
~~199~~ 202. A programmable infusion system in accordance with claim
~~198~~, wherein said comparing means is coupled to said telemetry
E₁₁₂ means for telemetering information ^{outputted} ~~deduced~~ by said comparing
means out of said living body.

²⁰³
~~189~~ 203. A programmable infusion system in accordance with claim
~~273~~, wherein said pump means executes in pulses, said recording
means comprising a pulse recorder comprising:

E ¹ means for counting the number of times said ^{pump} ~~pumping~~ means
pumps over a preselected time period, said counting means
storing the count; and

E ¹ means for counting the number of times said ^{pump} ~~pumping~~ means is
commanded to pump over said preselected time period.

²⁰⁴
D1 ~~203~~ 204. A programmable infusion system in accordance with claim
E ~~202~~, wherein said pulse recorder further comprises means for
comparing the ^{numbers} ~~number~~ recorded by both said counting means.

²⁰⁵
E₁₁₂ ~~204~~ 205. A programmable infusion system in accordance with claim
~~289~~, wherein said comparing means is coupled to said telemetry
means for telemetering information ^{outputted} ~~deduced~~ by said comparing
means out of said living body.

²⁰⁶
~~203~~ 206. A programmable infusion system in accordance with claim
~~287~~, further comprising means for providing an alarm signal when
said numbers recorded by both said counting means are different.

²⁰⁷
~~206~~ 207. A programmable infusion system in accordance with claim
~~290~~, wherein said alarm signal comprises a subcutaneous
electrical stimulation.

208
203
292. A programmable infusion system in accordance with claim
297, wherein said recording means is coupled to said telemetry
means for telemetering information recorded by both said
counting means out of said living body.

209
203
293. A programmable infusion system in accordance with claim
297, wherein said first recited counting means comprises a
pressure transducer.

210
189
294. A programmable infusion system in accordance with claim
297, wherein said recording means is powered by said implanted
power source.

211
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295. A programmable infusion system in accordance with claim
294 further comprising means for maintaining the pressure within
said medication reservoir at a pressure level below the internal
pressure of said living body.

212
211
296. A programmable infusion system in accordance with claim
295, wherein said pressure maintaining means comprises:
P₁ a flexible diaphragm which divides said medication reservoir
into a medication chamber and a liquid-vapor pool chamber; and
P₂ a liquid vapor pool disposed within said liquid-vapor pool
chamber, the proportion of liquid to vapor in said liquid-vapor
pool varying in response to variations in the amount of said
selected medication disposed in said medication chamber.

213
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297. A programmable infusion system in accordance with claim
296, said infusion apparatus further comprising switch means
disposed within said medication reservoir, said switch means
being coupled to said telemetry means and being activated when
said flexible diaphragm is disposed in a preselected
relationship ^{relative} ~~relate~~ to said switch means, said telemetry means

telemetering a signal indicative of such an operational condition to said telemetry receiving means.

214
298. A programmable infusion system in accordance with claim 213, wherein said switch means is activated by pressure exerted thereon by said flexible diaphragm, said pressure being less than the ambient pressure of said body.

215
212 299. A programmable infusion system in accordance with claim 296, said infusion apparatus further comprising an antechamber through which access is gained to said medication reservoir, and a reservoir inlet valve located between said antechamber and said medication chamber, said reservoir inlet valve being operable ~~and~~ when the pressure in said antechamber exceeds the pressure in the ^{said medication} reservoir chamber by more than a predetermined differential.

216
215 300. A programmable infusion system in accordance with claim 299, wherein the ^{volume} valve of said antechamber is less than 10% the ^{volume medication} valve of said ^{medication} reservoir chamber.

217
215 301. A programmable infusion system in accordance with claim 299, further comprising an inlet filter means operably disposed between said antechamber and said medication chamber for preventing impurities in said selected medication in said antechamber from passing into said medication chamber when said reservoir inlet valve is opened, said filter means also preventing said selected medication in said medication chamber from rapidly entering said living body in the event of a leak in said inlet valve.

218
110 302. A programmable infusion system in accordance with claim 299, further comprising means for programmed pumping of fixed-volume pulses of medication into said living body.

219
110 303. A programmable infusion system in accordance with claim
194, further comprising means for injecting medication into said
medication reservoir, said injecting means being coupled to said
telemetering receiver means, and programming means coupled to
said ^{telemetry} ~~telemetering~~ means for indicating when ejection of
medication into said medication reservoir is appropriate.

220
110 304. A programmable infusion system in accordance with claim
194, wherein said programming means is powered by said supply
means.

221
305. A programmable infusion system for providing medication
to a living body ^{of a patient} comprising:

P₁ an infusion apparatus for implantation in said living body,
said apparatus including

P₂ a medication reservoir for storing selected medication,

P₂ means for infusing said selected medication stored in
said medication reservoir into said living body, said infusion
means having a fluid handling mechanism for delivering said
selected medication and at least one remotely commandable
operational characteristic,

P₂ command receiver means coupled to said infusion means
for receiving command signals, and

P₂ means for telemetering operational information
pertaining to said infusion apparatus out of said living body,
said operational information including information about the
operation of said fluid handling mechanism of said infusion
means;

P₁ command source means external to said living body for
transmitting said command signals to be received by said command
receiver means; and

P means for receiving said telemetered operational information external to said living body.

²²²
~~221~~ 306. A programmable infusion system in accordance with claim 305, wherein said fluid handling mechanism comprises means for pumping said selected medication.

Sub E16
(CLAIM)
222-224
on
yellow
307. A programmable infusion system in accordance with claim ~~306~~, wherein ~~the amount of medication pumped by said pump means~~ ^{said pump means further comprises pressure limiting means for controlling} ~~is controlled by a pressure limit in said pump means.~~

~~225~~ 224
308. A programmable infusion system in accordance with claim ²²²~~306~~, wherein said pump means operates in a pulsatile mode.

225
309. A programmable infusion system in accordance with claim ²²⁴~~308~~, wherein said pump means pumps a fixed volume of said selected medication each time said pump means is pulsed.

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310. A programmable infusion system in accordance with claim ²²²~~306~~, wherein said pump means comprises variable volume means for storing said selected medication within said pump means, an increase in volume of said variable volume means permitting drawing of said selected medication into said pump means, a decrease in volume of said variable volume means permitting expulsion of said selected medication from said pump means.

Sub E17
311. A programmable infusion system in accordance with claim 310, wherein said variable volume means comprises at least one flexible wall, movement of said ^{at least one} flexible wall varying the value of said variable volume means, and means for moving said ^{at least one} flexible wall.

312. A programmable infusion system in accordance with claim 311, further comprising spring means for urging said ^{at least one flexible} wall in a manner which decreases the volume of said variable volume means, the magnitude of the force applied to and stored by said spring means increasing as the volume of said variable volume means increases due to the displacement of said ^{at least one} flexible wall thereof by said moving means.

313. A programmable infusion system in accordance with claim 312, wherein said flexible wall comprises a bellows assembly having mounted on one end thereof a plate, the other end of said bellows being in communication with said selected medication, the walls of said bellows serving as said spring means.

224 230
314. A programmable infusion system in accordance with claim 312, wherein said plate has a surface in contact with said selected medication when drawn into said variable volume means.

231
315. A programmable infusion system in accordance with claim 314, wherein said bellows ^{assembly} is inhibited from moving said plate when the pressure (p) in said ^{variable} volume means exceeds the spring force (F) of said bellows ^{assembly} divided by the wetted area (A) of said surface of said plate in contact with said selected medication, that is when $p > \frac{F}{A}$.

CLAIMS 2/8
232 233
316. A programmable infusion system in accordance with claim 313, wherein ~~said moving means comprises~~ said plate ^{is} being magnetizable, and a coil disposed proximate to said plate, said coil selectively radiating a pulsing magnetic field, pulsing of said coil causing said plate to be moved.

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317. A programmable infusion system in accordance with claim 316, wherein said plate comprises a permanent magnet.

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318. A programmable infusion system in accordance with claim 313, further comprising means for limiting the distance said plate can move in both ^athe volume increasing direction and ^athe volume decreasing direction.

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319. A programmable infusion system in accordance with claim 310, wherein said infusion means further comprises:

P₁ an interface pressure valve through which said selected medication enters said variable volume means from said medication reservoir, said interface pressure valve being normally closed;

P₂ an outlet chamber which is in communication with said living body; and

P₃ an outlet pressure valve located between said variable volume means and said outlet chamber, said outlet pressure valve being normally closed, an increase in volume of said variable volume means causing said interface pressure valve to open and medication to enter said variable volume means, a decrease in volume of said variable volume means causing said outlet pressure valve to open and said interface pressure valve to close, so as to permit medication to enter said outlet chamber as a pressure pulse.

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320. A programmable infusion system in accordance with claim 319, wherein said outlet chamber comprises an elastic wall having a fluidic capacitive effect on the flow of said selected medication and a filter element through which liquid flow to the said living body is resisted, said elastic wall and said filter comprising a fluid resistance-capacitance arrangement with respect to said flow of said selected medication from said outlet chamber into said living body.

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225 237
321. A programmable infusion system in accordance with claim 320, further comprising means for feeding said selected medication into said living body from said pump means in a flow which decays exponentially over time.

238
237 322. A programmable infusion system in accordance with claim 321, wherein said feeding means comprises a mechanical resistance (R) and a mechanical capacitance (C) circuit resulting in an exponentially decaying outflow of medication for each said fixed volume pulse.

239
226 323. A programmable infusion system in accordance with claim 310, wherein said infusion means further comprises an outlet chamber which is in communication with said living body, said pump means expelling said selected medication into said outlet chamber means, and means for monitoring the operation of said pump means, said monitoring means being disposed in said outlet chamber and providing a signal in response to a pressure pulse in said outlet chamber caused by said pump means, said monitoring means being operably coupled to said telemetry means.

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237 324. A programmable infusion system in accordance with claim 323, wherein said monitoring means comprises a pressure transducer.

241
239 325. A programmable infusion system in accordance with claim 323, further comprising first means for indicating the operation of said pump means when a decrease in volume of said variable volume means is not followed by a signal from said monitoring means corresponding to a pressure pulse of said selected medication expelled into said outlet chamber, said first indicating means being operably coupled to said telemetry means.

241 326. A programmable infusion system in accordance with claim 325, further comprising second means for indicating the operation of said pump means wherein a signal is provided by said monitoring means absent a decrease in volume of said variable volume means ~~caused by said moving means~~, said second indicating means being operably coupled to said telemetry means.

243 327. A programmable infusion system in accordance with claim 326, further comprising means for monitoring the operation of said pump means, said monitoring means being operably coupled to said telemetry means.

243 328. A programmable infusion system in accordance with claim 327, wherein said monitoring means comprises pressure sensing means disposed in the path of flow of said selected medication into said ~~living~~ ^{living} body, said pressure sensing means providing a signal in response to a pressure pulse in said path of flow.

D1 Sub E19
CLAIMS

245 329. A programmable infusion system in accordance with claim 328, ^{(insert body of claim 104 "wherein ... (end)"), said system} further comprising first means for indicating the operation of said pump means when a decrease in volume of said variable volume means is not followed by a signal from said monitoring means corresponding to a pressure pulse of said selected medication expelled into said outlet chamber, said first indicating means being operably coupled to said telemetry means.

245 330. A programmable infusion system in accordance with claim 329, further comprising second means for indicating the operation of said pump means ^{when} ~~wherein~~ a signal is provided by said monitoring means absent a decrease in volume of said variable volume means ~~caused by said moving means~~, said second indicating means being operably coupled to said telemetry means.

247
331. A programmable infusion system in accordance with claim 330, wherein one of said command signals transmitted by said command source means comprises a signal which corresponds to a selected operational rate at which said infusion means will infuse said selected medication into said living body.

248
332. A programmable infusion system in accordance with claim 331, wherein said command source and said telemetry receiving means are embodied in a patient programming unit external to said living body, said patient programming unit having a plurality of operational medication dose inputs each corresponding to a medication infusion rate selectable and requestable by the patient, said patient programming unit for selectively transmitting a command signal corresponding to a selected ^{one of} said medication dose ^{inputs} ~~input~~.

249
333. A programmable infusion system in accordance with claim 332, wherein said infusion apparatus further comprises electronic control means coupled to said infusion means and said command receiver means, said electronic control means ^{including means} for maintaining a history of the infusion rate at which said infusion means has operated, said electronic control means ^{including means} for precluding the infusion of said selected medication by said infusion means if said rate requested by said patient programming unit exceeds a predetermined safe medication infusion rate based on said maintained history.

250
334. A programmable infusion system in accordance with claim 333, wherein said electronic control means is coupled to said telemetry means, said patient programming unit including means for indicating to said patient if said selected infusion rate exceeds said predetermined safe medication infusion rate, said ~~electronic~~ ^{selective} control means selectively sending a signal to said

indicating means via said telemetry means and said telemetry receiving means, said telemetry receiving means being coupled to said indicating means.

E ^{246 251}
~~335~~ 335. A programmable infusion system in accordance with claim ~~334~~, wherein said patient programming unit further comprises annunciator means and visual display means for providing information regarding previously selected medication infusion rates, for indicating whether a proper programming of a presently requested infusion rate has been communicated to said command receiver, and for selectively providing information as to the time and rate of previously selected medication infusion.

D1 ²⁵²
~~336~~ 336. A programmable infusion system in accordance with claim ~~335~~, further comprising means for selectively supplying power to said command receiver means, said supply means being coupled to an external power source, said supply means being external to said living body, said infusion means being powered by an implanted power source.

²⁵³
~~337~~ 337. A programmable infusion system, in accordance with Claim ~~336~~ ²⁵², wherein said supply means provides an alternating field.

²⁵⁴
~~338~~ 338. A programmable infusion system, in accordance with claim ~~337~~ ²⁵³, wherein said infusion apparatus further comprises detector means for detecting said alternating field and for converting the same into electrical energy, said detecting means being coupled to said command receiver.

²⁵⁵
~~339~~ 339. A programmable infusion system in accordance with claim ~~338~~ ²⁵⁴, wherein said infusion apparatus further comprises means for rectifying said electrical energy into a d.c. power signal.

²⁵⁴
~~340~~. A programmable infusion system in accordance with claim ~~339~~, wherein said d.c. power signal is coupled to said implanted power source to effect the charging thereof.

²⁵⁷
~~255~~³⁴¹. A programmable infusion system in accordance with claim ~~339~~, wherein said telemetry means is coupled to said rectifier means and is powered by said d.c. power signal.

²⁵⁸
~~252~~³⁴². A programmable infusion system in accordance with claim ~~336~~, wherein said telemetry means is also supplied power by said supply means.

²⁵⁹
~~252~~³⁴³. A programmable infusion system in accordance with claim ~~336~~, further comprising means for selectively recharging said implanted power source, said recharging means being powered by said supply means.

²⁶⁰
~~252~~³⁴⁴. A programmable infusion system in accordance with claim ~~305~~, wherein one of said ^{at least one} remotely commandable operational characteristic~~s~~ comprises an infusion rate variable on command, said infusion apparatus further comprising means for inhibiting sad infusion apparatus further comprising means for inhibiting said infusion means from infusing said selected medication if a preselected medication infusion rate is exceeded by a commanded infusion rate, said inhibiting means being operably coupled to said infusion means.

²⁶¹
~~260~~³⁴⁵. A programmable infusion system in accordance with claim ~~344~~, wherein said inhibiting means comprises at least one means for defining a fixed infusion rate limit.

²⁶²
~~261~~³⁴⁶. A programmable infusion system in accordance with claim ~~345~~, wherein said ^{at least one} means for defining a fixed infusion rate limit is hardwired.

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347. A programmable infusion system in accordance with claim 344, wherein said preselected medication infusion rate is remotely selectable.

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260
348. A programmable infusion system in accordance with claim 344, wherein said preselected medication infusion rate comprises a remotely selectable rate and a fixed rate, said remotely selectable rate being limited by said fixed rate.

265-267
349. A programmable infusion system in accordance with claim 348, wherein said inhibiting means comprises:
at least one programmable rate memory unit coupled to said command receiver means, each of said ^{at least one} programmable rate memory units for receiving and storing an infusion rate input command corresponding to said remotely selectable rate;
at least one limit control unit, each of ^{said at least one limit control unit providing} which provides a fixed rate limit; and
means for comparing each of said infusion rate input commands to a corresponding said fixed rate limit, infusion of said medication at a rate exceeding said fixed rate limit being inhibited.

266 260
265
350. A programmable infusion system in accordance with claim 349, further comprising command decoder means for coupling said ^{units} at least one said programmable rate memory ^{unit} to said command receiver means, said command decoder means for decoding said command signals received by said command receiver means into said infusion rate inputs for receipt by and storage in ^{corresponding} said at least one programmable rate memory ^{units} ^{units}.

267
265
351. A programmable infusion system in accordance with claim 349, wherein each of said ^{at least one} limit control units are hardwired. ✓

²⁶⁴
~~265~~ 349. A programmable infusion system in accordance with claim 347, further comprising means for generating an alarm signal when any infusion rate input command exceeds a corresponding fixed rate limit.

²⁶⁹
~~265~~ 353. A programmable infusion system in accordance with claim 349, wherein said inhibiting means precludes infusion of said medication by said infusion means when the selected said commandable infusion rate exceeds said preselected ^{medication} infusion rate during a ~~fixed~~ ^{of a predetermined length} window of time which shifts continuously.

²⁷⁰
~~260~~ 354. A programmable infusion system in accordance with claim 344, wherein said inhibiting means precludes infusion of said medication by said infusion means when the selected said commandable infusion rate exceeds said preselected infusion rate during a ~~fixed~~ window of time which shifts continuously. ✓

Sub E21
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355. A programmable infusion system in accordance with claim 344, wherein said fluid handling mechanism of said infusion means includes a pump means which executes in pulses, said inhibiting means comprising a programmable memory rate unit coupled to said command receiver for storing initially a ^{dose limit} number corresponding to a first maximum number of infusion pulses preselected as allowable during a first shifting time window of a predetermined length, pulse quantities being subtracted from said ~~first~~ number stored in said programmable memory rate unit as infusion pulses are executed by said infusion means, pulse quantities being added to said ~~first~~ number as time elapses such that said number does not exceed said first maximum number, said subtraction and addition being accomplished in running integral fashion, said inhibiting means not permitting pulsing of said pump means ^{at a rate} a number of times in excess of ^{the rate represented by} said number stored in said programmable memory rate unit. ^{dose limit}

356. A programmable infusion system in accordance with claim 355, wherein said memory rate unit also records the number of pulses which have been inhibited and causes said pump means of said fluid handling mechanism to execute said pulses when said pulses can be subtracted from said ^{dose limit} number stored in said programmable memory rate unit as a result of the elapse of time.

357. A programmable infusion system in accordance with claim 355, wherein said programmable memory rate unit also stores initially another number corresponding to a second maximum number of infusion pulses preselected as allowable during a second shifting time window of a predetermined length, said second ~~fixed~~ shifting time window being longer in length than said first shifting time window, pulse quantities being subtracted from said another ^{dose limit} number stored in said programmable memory rate unit as infusion pulses are executed by said infusion means, pulse quantities being added to said ^{another dose limit} second number as time elapses such that said another ^{dose limit} number does not exceed said first maximum number, said subtraction and addition being accomplished in running integral fashion, said inhibiting means not permitting pulsing of said pump means ^{at a rate} a number of times in excess of said another ^{the rate represented by} number stored in said programmable memory rate unit. ^{dose limit}

273 274 358. A programmable infusion system in accordance with claim 357, wherein said rate memory unit also records the number of pulses which have been inhibited and causes said pump means of said fluid handling mechanism to execute said pulses when said pulses can be subtracted from ^{both} said ^{dose limit} numbers stored in said programmable memory rate unit.

274 275 359. A programmable infusion system in accordance with claim 358, wherein said inhibiting means further comprises at least

one fixed infusion rate limit which limits the total maximum infusion rate of said infusion means.

275 ²⁷⁶
360. A programmable infusion system in accordance with claim 359, wherein said fixed infusion rate limit is hardwired.

277
273 ²⁷⁷
361. A programmable infusion system in accordance with claim 357, further comprising means for generating an alarm signal when any commanded infusion rate results in the inhibiting of pulsing of said pump means by said inhibiting means.

278
277 ²⁷⁸
362. A programmable infusion system in accordance with claim 361, wherein said alarm signal comprises a subcutaneous electrical stimulation.

D/ 279
273 ²⁷⁹
363. A programmable infusion system in accordance with claim 357, further comprising command decoder means for coupling said command receiver means to said programmable memory rate unit, said command decoder means for decoding said command signals received by said command receiver means into said first and second ^{maximum} numbers of infusion pulses.

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F ²⁶⁰
364. A programmable infusion system in accordance with claim 344, wherein said inhibiting means is operably coupled to said telemetry means, said inhibiting means providing a signal to said telemetry means for telemetering to said telemetry receiving means operational information pertaining to the functions of said inhibiting means.

281
265 ²⁸¹
365. A programmable infusion system in accordance with claim 344, further comprising means for generating an alarm signal when said inhibiting means inhibits said infusion means.

282
266. A programmable infusion system in accordance with claim 265, further comprising means for recording when said inhibiting means inhibits said infusion means.

283
267. A programmable infusion system in accordance with claim 266, wherein said recording means is coupled to said telemetry means, said recording means providing a signal to said telemetry means for telemetering to said telemetry receiving means operational information pertaining to said inhibiting means as recorded by said recording means.

284
268. A programmable infusion system in accordance with claim 267, said infusion apparatus further comprising means for generating a distinctive alarm signal pattern for each of a plurality of improper ^{operational} ~~operation~~ conditions.

285-297
369. A programmable infusion system in accordance with claim 368, wherein said alarm signal ^{is delivered} ~~is delivered~~ to said living body subcutaneously. ^{pattern}

370. A programmable infusion system in accordance with claim 369, further comprising means for detecting a medication leak, ^{said means for detecting means being} coupled to said alarm means, wherein one of said improper ^{al} ~~operation~~ conditions comprises a medication leak out of said medication reservoir.

371. A programmable infusion system in accordance with claim 369, further comprising means for detecting a body fluid leak, ^{said body fluid leak detecting means being} coupled to said alarm ^{generator} ~~means~~, wherein one of said improper ^{al} ~~operation~~ conditions comprises a leak of body fluids into said infusion apparatus.

372. A programmable infusion system in accordance with claim 369, further comprising means for detecting the rate at which said infusion means is operating, ^{said rate detecting means being} coupled to said alarm ^{generating} means, wherein one of said improper operation ^{al} conditions comprises operation of said infusion means at an improper rate.

④ 373. A programmable infusion system in accordance with claim 369, wherein one of said improper operation ^{al} conditions comprises receiving of a command by said command receiver ^{means} which cannot be executed.

⑤ 374. A programmable infusion system in accordance with claim 369, further comprising ^a battery means for powering said infusion means and means for determining the voltage of said battery ^{means}, ^{said voltage detecting means being} coupled to said alarm ^{generating} means, wherein one of said improper operation ^{al} conditions ^{means} comprises low battery ^{al} voltage.

D1

⑥ 375. A programmable infusion system in accordance with claim 369, further comprising means for detecting the amount of medication disposed in said reservoir, ^{said medication amount detecting means being} coupled to said alarm ^{generating} means, wherein one of said improper operation conditions comprises a preselected amount of medication remaining in said medication reservoir.

⑦ 376. A programmable infusion system in accordance with claim 368, further comprising means for detecting a medication leak, ^{said medication detecting means being} coupled to said alarm ^{generating} means, wherein one of said improper operation ^{al} conditions comprises a medication leak out of said medication reservoir.

⑧ 377. A programmable infusion system in accordance with claim 368, further comprising means for detecting a body fluid leak, ^{said body fluid leak detecting means being} coupled to said alarm ^{generating} means, wherein one of said improper

operation^{al} conditions comprises a leak of body fluids into said infusion apparatus.

378. A programmable infusion system in accordance with claim 368, further comprising means for detecting the rate at which said infusion means is operating, ^{said rate detecting means being} coupled to said alarm means, wherein one of said improper operation^{al} conditions comprises ^{generating} operation of said invasion means at an improper rate.

379. A programmable infusion system in accordance with claim 368, wherein one of said improper operation^{al} conditions comprises receiving of a command by said command receiver^{means}, which cannot be executed.

380. A programmable infusion system in accordance with claim 368, further comprising ^a battery means for powering said infusion means and means for determining the voltage of said battery ^{determining means being} means, ^{coupled to said alarm means, wherein one of said improper operation^{al} conditions, ^{generating} comprises low battery^{means} voltage.}

381. A programmable infusion system in accordance with claim 368, further comprising means for detecting the amount of medication disposed in said reservoir, ^{said medication detecting means being} coupled to said alarm means, wherein one of said improper operation^{al} conditions ^{generating} comprises a preselected amount of medication remaining in said medication reservoir.

284 298
382. A programmable infusion system in accordance with claim 368, further comprising means for simulating said improper operational conditions for test ^{purposes} purposes.

221 299 ✓
383. A programmable infusion system in accordance with claim 365, wherein said fluid handling mechanism includes means for

pumping a preselected amount of medication into said living body, said infusion apparatus further comprising means for recording the rate at which pumping is effected by said pumping means.

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M

CLAIMS
Sub E 23
300-301
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384. A programmable infusion system in accordance with claim 383, wherein said recording means comprises:

means for storing the rate at which said pumping means pumps over a preselected time period;

means for storing a programmable input corresponding to a minimum medication infusion rate; and

means for comparing the rate recorded by said ^{first recited storing} recording means to the rate stored in said ^{second recited} storing means.

385. A programmable infusion system in accordance with claim 384, further comprising means for providing an alarm signal when

^{input corresponding to said} said rate recorded by said ^{first recited storing is} recording means ^{if less than said} ^{programmable} minimum medication infusion rate. ^{indicated by said second recited storing means.}

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386. A programmable infusion system in accordance with claim

384, wherein said recording means is coupled to said telemetry means for telemetering information ^{recorded by} ~~received~~ by said recording means out of said living body.

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387. A programmable infusion system in accordance with claim 383, wherein said recording means comprises:

means for storing the rate at which said ^{pump} ~~pumping~~ means pumps over a preselected time period; and

means for storing the rate at which said ^{pump} ~~pumping~~ means is signalled to pump over said preselected time period.

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E

388. A programmable infusion system in accordance with claim 384, further comprising means for comparing the rates recorded by both said storing means.

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305
304
309. A programmable infusion system in accordance with claim
308, wherein said comparing means is coupled to said telemetry
means for telemetering information ^{outputted} ~~deduced~~ by said comparing
means out of said living body.

306
304
310. A programmable infusion system in accordance with claim
308, further comprising means for providing an alarm signal when
the rate at which said ^{pump} ~~pumping~~ means pumps is different than the
rate at which said ^{pump} ~~pumping~~ means ^{is} ~~is~~ signalled to pump.

307
303
311. A programmable infusion system in accordance with claim
307, wherein said recording means is coupled to said telemetry
means for telemetering information recorded by ~~both~~ said
recording means out of said living body.

308
309
312. A programmable infusion system in accordance with claim
303, wherein said pump means executes in pulses, said recording
means comprising a pulse rate detector comprising:
P means for counting the number of times said ^{pump} ~~pumping~~ means
pumps over a preselected time period, said counting means
storing the count;
P minimum rate memory means for storing a programmable number
input corresponding to a minimum medication infusion rate; and
P means for comparing the number counted by said counting
means with said programmable number input stored in said minimum
rate memory means.

309
308
313. A programmable infusion system in accordance with claim
312, further comprising means for providing an alarm signal when
said count is less than said programmable number input stored in
said minimum rate memory means.

309 ³¹⁰ 394. A programmable infusion system in accordance with claim 393, wherein said alarm signal comprises a subcutaneous electrical stimulation.

309 ³¹¹ 395. A programmable infusion system in accordance with claim 393, wherein said counting means comprises a pressure transducer.

E 308 ³¹² 396. A programmable infusion system in accordance with claim 393, wherein said comparing means is coupled to said telemetry means for telemetering information ^{not outputted} ~~deduced~~ by said comparing means out of said living body.

D1 309 ³¹³ 397. A programmable infusion system in accordance with claim 393, wherein said pump means executes in pulses, said recording means comprising a pulse recorder comprising:

E 309 ³¹³ 397. A programmable infusion system in accordance with claim 393, wherein said pump means executes in pulses, said recording means comprising a pulse recorder comprising:

E 309 ³¹³ 397. A programmable infusion system in accordance with claim 393, wherein said pump means executes in pulses, said recording means comprising a pulse recorder comprising:

E 309 ³¹⁴ 398. A programmable infusion system in accordance with claim 397, wherein said pulse recorder further comprises means for comparing the ^{numbers} ~~number~~ recorded by both said counting means.

E 309 ³¹⁵ 399. A programmable infusion system in accordance with claim 398, wherein said comparing means is coupled to said telemetry means for telemetering information ^{outputted} ~~deduced~~ by said comparing means out of said living body.

127

✓ ³¹⁶
~~315~~ ³¹⁶ 400. A programmable infusion system in accordance with claim
~~397~~, further comprising means for providing an alarm signal when
said numbers recorded by both said counting means are different.

³¹⁷
~~316~~ ³¹⁷ 401. A programmable infusion system in accordance with claim
400, wherein said alarm signal comprises a subcutaneous
electrical stimulation.

³¹⁸
- ³¹⁵ ³¹⁸ 402. A programmable infusion system in accordance with claim
~~397~~, wherein said recording means is coupled to said telemetry
means for telemetering information recorded by both said
counting means out of said living body.

D1 ³¹⁹
✓ ³¹⁵ ³¹⁹ 403. A programmable infusion system in accordance with claim
~~397~~, wherein said first recited counting means comprises a
pressure transducer.

(M) ³²⁰
²²¹ ³²⁰ 404. A programmable infusion system in accordance with claim
~~305~~, further comprising means for maintaining the pressure within
said medication reservoir at a pressure level below the internal
pressure of said living body.

³²¹
³²⁰ ³²¹ 405. A programmable infusion system in accordance with claim
~~404~~, wherein said pressure maintaining means comprises:

P. a flexible diaphragm which divides said medication reservoir
into a medication chamber and a liquid-vapor pool chamber; and

P. a liquid vapor pool disposed within said liquid-vapor pool
chamber, the proportion of liquid to vapor in said liquid-vapor
pool varying in response to variations in the amount of said
selected medication disposed in said medication chamber.

³²²
³²⁰ ³²² 406. A programmable infusion system in accordance with claim
~~305~~, said infusion apparatus further comprising switch means

disposed within said medication reservoir, said switch means being coupled to said telemetry means and being activated when said flexible diaphragm is disposed in a preselected relationship relative to said switch means, said telemetry means telemetering a signal indicative of such an operational condition to said telemetry receiving means.

323
322-407. A programmable infusion system in accordance with claim 406, wherein said switch means is activated by pressure exerted thereon by said flexible diaphragm, said pressure being less than the ambient pressure of said body.

324
323-408. A programmable infusion system in accordance with claim 405, said infusion apparatus further comprising an antechamber through which access is gained to said medication reservoir, and a reservoir inlet valve located between said antechamber and said medication chamber, said reservoir inlet valve being operable ~~and~~ when the pressure in said antechamber exceeds the pressure in ^{said medication} ~~the reservoir~~ chamber by more than a predetermined differential.

325
324-409. A programmable infusion system in accordance with claim 408, wherein the volume of said antechamber is less than 10% the volume of said ^{medication} ~~reservoir~~ chamber.

326
325-410. A programmable infusion system in accordance with claim 409, further comprising an inlet filter means operably disposed between said antechamber and said medication chamber for preventing impurities in said selected medication in said ~~antechamber~~ ^{antechamber} from passing into said medication chamber when ^{said} ~~the~~ reservoir inlet valve is opened, said filter means also preventing said selected medication in said medication chamber from rapidly entering said living body in the event of a leak in said inlet valve.

327
321
305, 411. A programmable infusion system in accordance with claim
further comprising means for programmed pumping of
fixed-volume pulses of medication into said living body.

✓ 328
412. A programmable infusion system for providing medication
to a living body ^{for patient} comprising:

P₁ an infusion apparatus for implantation in said living body,
said apparatus including

P₂ a medication reservoir for storing selected medication,

P₂ means for infusing said selected medication stored in
said medication reservoir into said living body, said infusion
means having an infusion rate variable upon command,

P₂ command receiver means coupled to said infusion means
for receiving command signals, and

P₂ means for inhibiting said infusion means from infusing
said selected medication if a preselected medication infusion
rate is exceeded, said inhibiting means being operably coupled
to said infusion means; and

P₁ command source means external to said living body for
transmitting said command signals to be received by said command
receiver means.

329
328
413. A programmable infusion system in accordance with claim
412, wherein said inhibiting means comprises at least one means
for defining a fixed infusion rate limit.

330
329
414. A programmable infusion system in accordance with claim
413, wherein said ^{at least one} means for defining a fixed infusion rate limit
is hardwired.

331
330 415. A programmable infusion system in accordance with claim 412, wherein said preselected medication infusion rate is remotely selectable.

332 332
328 416. A programmable infusion system in accordance with claim 412, wherein said preselected medication infusion rate comprises a remotely selectable rate and a fixed rate, said remotely selectable rate being limited by said fixed rate.

CLAIM 24
333 333
417. A programmable infusion system in accordance with claim 416, wherein said inhibiting means comprises:

at least one programmable rate memory unit coupled to said command receiver means, each of said ^{at least one} programmable rate memory units for receiving and storing an infusion rate input command corresponding to said remotely selectable rate;

at least one limit control unit, each of ^{said at least one limit control unit providing} which provides a fixed rate limit; and

means for comparing each of said infusion rate input commands to a corresponding said fixed rate limit, infusion of said medication at a rate exceeding said fixed rate limit being inhibited.

334
333 418. A programmable infusion system in accordance with claim 417, further comprising command decoder means for coupling said ^{each of} at least one ~~said~~ programmable rate memory ^{units} ~~unit~~ to said command receiver means, said command decoder means for decoding said command signals received by said command receiver means into said infusion rate inputs for receipt by and storage in said at ^{each of} least one programmable rate memory ^{corresponding} ~~unit~~. ^{corresponding}

335
333 419. A programmable infusion system in accordance with claim 417, wherein each of said ^{at least one} limit control units ^{is} ~~are~~ hardwired.

336 335 336

420. A programmable infusion system in accordance with claim 417, further comprising means for generating an alarm signal when any infusion rate input command exceeds a corresponding fixed rate limit.

337 337

421. A programmable infusion system in accordance with claim 417, wherein said inhibiting means precludes infusion of said medication by said infusion means when the selected said commandable infusion rate exceeds said preselected medication infusion rate during a ~~fixed~~ ^{of a predetermined length} window of time which shifts continuously.

Sub E 25
CLAIMS
3,38-3,41
4,11-4,14
D1

422. A programmable infusion system in accordance with claim 412, wherein said inhibiting means precludes infusion of said medication by said infusion means when the selected said ~~commandable~~ ^{medication} infusion rate exceeds said preselected ~~infusion rate~~ ^{of a predetermined length} during a ~~fixed~~ window of time which shifts continuously.

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N
P

423. A programmable infusion system in accordance with claim 412, wherein said infusion means includes a pump means which executes in pulses, said inhibiting means comprising a programmable memory rate unit coupled to said command receiver for storing initially a ^{base limit} number corresponding to a first maximum number of infusion pulses preselected as allowable during a first shifting time window of a predetermined length, pulse quantities being subtracted from said number stored in said programmable memory rate unit as infusion pulses are executed by said infusion means, pulse quantities being added to said stored number as time elapses such that said number does not exceed said first maximum number, said subtraction and addition being accomplished in running integral fashion, said inhibiting means not permitting pulsing of said pump means ^{at a rate} a number of times in excess of ^{the rate represented by} said number stored in said programmable memory rate unit.

134

424. A programmable infusion system in accordance with claim 423, wherein said memory rate unit also records the number of pulses which have been inhibited and causes said pump means of said infusion means to execute said pulses when said pulses can be subtracted from said ^{dose limit} number stored in said programmable memory rate unit as a result of the elapse of time.

425. A programmable infusion system in accordance with claim 423, wherein said programmable memory rate unit also stores initially another ^{dose limit} number corresponding to a second maximum number of infusion pulses preselected as allowable during a second shifting time window of a predetermined length, said second shifting time window being longer in length than said first shifting time window, pulse quantities being subtracted from said another ^{dose limit} number stored in said programmable memory rate unit as infusion pulses are executed by said infusion means, pulse quantities being added to said another ^{dose limit} stored number as time elapses such that said another ^{dose limit} number does not exceed said first maximum number, said subtraction and addition being accomplished in running integral fashion, said inhibiting means not permitting pulsing of said pump means ^{at a rate} a number of times in excess of said another ^{the rate represented} number stored in said programmable memory ~~rate unit~~.

341 426. A programmable infusion system in accordance with claim 425, wherein said rate memory unit also records the number of pulses which have been inhibited and causes said pump means of said infusion means to execute said pulses when said pulses can be subtracted from ^{both said dose limit numbers} said number stored in said programmable memory rate unit.

342 427. A programmable infusion system in accordance with claim 426, wherein said inhibiting means further comprises at least

one fixed infusion rate limit which limits the total maximum infusion rate of said infusion means.

343 ³⁴⁴
~~426~~. A programmable infusion system in accordance with claim
343 ~~427~~, wherein said fixed infusion rate limit is hardwired.

341 ³⁴⁵
~~425~~. A programmable infusion system in accordance with claim
341 ~~425~~, further comprising means for generating an alarm signal
when any commanded infusion rate results in the inhibiting of
pulsing of said pump means by said inhibiting means.

345 ³⁴⁶
~~429~~. A programmable infusion system in accordance with claim
345 ~~429~~, wherein said alarm signal comprises a subcutaneous
electrical stimulation.

341 ³⁴⁷
~~425~~. A programmable infusion system in accordance with claim
341 ~~425~~, further comprising command decoder means for coupling said
command receiver means to said programmable memory rate unit,
said command decoder means for decoding said command signals
received by said command receiver means into said first and
second ^{maximum} numbers of infusion pulses.

328 ³⁴⁸
~~412~~. A programmable infusion system in accordance with claim
328 ~~412~~, further comprising means for telemetering operational
information pertaining to said infusion apparatus out of said
living body, said operational information including information
pertaining to the functions of said inhibiting means, and means
for receiving said telemetered operational information external
to said living body.

328 ³⁴⁹
~~412~~. A programmable infusion system in accordance with claim
328 ~~412~~, wherein one of said command signals transmitted by said
command source means comprises a signal which corresponds to a

selected operational rate at which said infusion means will
infuse said selected medication into said living body.

350
328 434. A programmable infusion system in accordance with claim
432, further comprising means for telemetering operational
information pertaining to said infusion apparatus out of said
living body, and means for receiving said telemetered
operational information external to said living body, wherein
said command source and said telemetry receiving means are
embodied in a patient programming unit external to said living
body, said patient programming unit having a plurality of
operational medication dose inputs each corresponding to a
medication infusion rate selectable and requestable by the
patient, said patient programming unit for selectively
transmitting a command signal corresponding to a selected ^{one of} said
medication dose ^{inputs} ~~input~~.

351
D1 350 435. A programmable infusion system in accordance with claim
434, wherein said infusion apparatus further comprises
electronic control means coupled to said infusion means and said
command receiver means, said ^{electronic} ~~electric~~ control means ^{including means} for
maintaining a history of the infusion rate at which said
infusion means has operated, said ^{including means} ~~electronic~~ control means ^{including means} for
precluding the infusion of said selected medication by said
infusion means if said rate requested by said patient
programming unit exceeds a predetermined safe medication
infusion rate based on said maintained history.

352
351 436. A programmable infusion system in accordance with claim
435, wherein said electronic control means is coupled to said
telemetry means, said patient programming unit including means
for indicating to said patient if said selected infusion rate
exceeds said predetermined safe medication infusion rate, said

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~~selective~~ ^{electronic}

control means selectively sending a signal to said indicating means via said telemetry means and said telemetry receiving means, said telemetry receiving means being coupled to said indicating means.

✓

331 ³⁵³

437. A programmable infusion system in accordance with claim 435, wherein said patient programming unit further comprises annunciator means and visual display means for providing information regarding previously selected medication infusion rates, for indicating whether a proper programming of a presently requested infusion rate has been communicated to said command receiver, and for selectively providing information as to the time and rate of previously selected medication infusion.

D1

328 ³⁵⁴

438. A programmable infusion system in accordance with claim 432, further comprising means for selectively supplying power to said command receiver means, said supply means being coupled to an external power source, said supply means being external to said living body, said infusion means being powered by an implanted power source.

355 ³⁴⁴

439. A programmable infusion system, in accordance with claim 438, wherein said supply means provides an alternating field.

356 ³⁵⁵

440. A programmable infusion system, in accordance with claim 439, wherein said infusion apparatus further comprises detector means for detecting said alternating field and for converting the same into electrical energy, said detecting means being coupled to said command receiver.

357 ³⁵⁶

441. A programmable infusion system in accordance with claim 440, wherein said infusion apparatus further comprises means for rectifying said electrical energy into a d.c. power signal.

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³⁵⁸
~~442~~. A programmable infusion system in accordance with
³⁵⁷
claim ~~441~~, wherein said d.c. power signal is coupled to said
implanted power source to effect the charging thereof.

³⁵⁹
³⁵⁷~~443~~. A programmable infusion system in accordance with claim
~~441~~, further comprising means for telemetering operational
information pertaining to said infusion apparatus out of said
living body, and means for receiving said telemetered
operational information external to said living body, said
telemetry means being coupled to said rectifier means and being
powered by said d.c. power signal.

³⁶⁰
³⁵⁴~~444~~. A programmable infusion system in accordance with claim
~~438~~, further comprising means for telemetering operational
information pertaining to said infusion apparatus out of said
living body, and means for receiving said telemetered
operational information external to said living body, said
telemetry means also being supplied power by said supply means.

³⁶¹
³⁵⁴~~445~~. A programmable infusion system in accordance with claim
~~438~~, further comprising means for selectively recharging said
implanted power source, said recharging means being powered by
said supply means.

³⁶²
³²⁸~~446~~. A programmable infusion system in accordance with claim
~~412~~, wherein said infusion means comprises a fluid handling
mechanism for delivering said selected medication, said
operational information including information about the
operation of said fluid handling mechanism.

✓ ³⁶³
³⁶²~~447~~. A programmable infusion system in accordance with claim
~~446~~, wherein said fluid handling mechanism comprises means for
pumping said selected medication.

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Sub E 26

448. A programmable infusion system in accordance with claim 447, wherein ~~the~~ ^{said pump means further comprises pressure limiting means for controlling} amount of medication pumped by said pump means ~~is controlled by a pressure limit in said pump means.~~

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449. A programmable infusion system in accordance with claim 447, wherein said pump means operates in a pulsatile mode.

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450. A programmable infusion system in accordance with claim 449, wherein said pump means pumps a fixed volume of said selected medication each time said pump means is pulsed.

✓
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451. A programmable infusion system in accordance with claim 447, wherein said pump means comprises variable volume means for storing said selected medication within said pump means, an increase in volume of said variable volume means permitting drawing of said selected medication into said pump means, decrease in volume of said variable volume means permitting expulsion of said selected medication from said pump means.

Sub E 27
CLAIMS
365-368
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452. A programmable infusion system in accordance with claim 451, wherein said variable volume means comprises at least one flexible wall, movement of said ^{at least one} flexible wall varying the volume of said variable volume means, and means for moving said ^{at least one} flexible wall.

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453. A programmable infusion system in accordance with claim 452, further comprising spring means for urging said ^{at least one flexible} wall in a manner which decreases the volume of said variable volume means, the magnitude of the force applied to and stored by said spring means increasing as the volume of said variable volume means increases due to the displacement of said ^{at least one} flexible wall thereof by said moving means.

143

370
E 369 454. A programmable infusion system in accordance with claim
453, wherein said ^{at least one} flexible wall comprises a bellows assembly
having mounted on one end thereof a plate, the other end of said
E bellows ^{assembly} being in communication with said selected medication,
E the walls of said bellows ^{assembly} serving as said spring means.

371
370 455. A programmable infusion system in accordance with claim
454, wherein said plate has a surface in contact with said
selected medication when drawn into said variable volume means.

372
E 371 456. A programmable infusion system in accordance with claim
455, wherein said bellows ^{assembly} is inhibited from moving said plate
when the pressure (p) in said variable volume means exceeds the
E spring force (F) of said bellows ^{assembly} divided by the wetted area (A)
of said surface of said plate in contact with said selected
medication, that is when $p > \frac{F}{A}$.

DI 373
E 370 457. A programmable infusion system in accordance with claim
454, wherein said moving means ^{said plate is magnetizable,} comprises said plate being
E ^{comprising} magnetizable, and a coil disposed proximate to said plate, said
coil selectively radiating a pulsing magnetic field, pulsing of
said coil causing said plate to be moved.

374
373 458. A programmable infusion system in accordance with claim
457, wherein said plate comprises a permanent magnet.

375
E 370 459. A programmable infusion system in accordance with claim
454, further comprising means for limiting the distance said
plate can move in both ^a ^a the volume increasing direction and ^a ^a the
volume decreasing direction.

376
367 460. A programmable infusion system in accordance with claim
451, wherein said infusion means further comprises:

^{valve}
 E ^P an interface pressure ~~valve~~ through which said selected medication enters said variable volume means from said medication reservoir, said interface pressure ^{valve} ~~valve~~ being normally closed;
^P an outlet chamber which is in communication with said living body; and
^P an outlet pressure valve located between said variable volume means and said outlet chamber, said outlet pressure valve being normally closed, an increase in volume of said variable volume means causing said interface pressure valve to open and medication to enter said variable volume means, a decrease in volume of said variable volume means causing said outlet pressure valve to open and said interface pressure valve to close, so as to permit medication to enter said outlet chamber as a pressure pulse.

D1 ³⁷⁷
³⁷⁶ 401. A programmable infusion system in accordance with claim ~~360~~, wherein said outlet chamber comprises an elastic wall having a fluidic capacitive effect on the flow of said selected medication and a filter element through which liquid flow to the said ^{living} ~~living~~ body is resisted, said elastic wall and said filter comprising a fluid resistance - capacitance arrangement with respect to said flow of said selected medication from said outlet chamber into said living body.

E M ³⁶⁶ ³⁷⁸
⁴⁶⁰ 462. A programmable infusion system in accordance with claim ~~461~~, further comprising means for feeding said selected medication into said living body from said pump means in a flow which decays exponentially over time.

³⁷⁹
³⁷⁸ 463. A programmable infusion system in accordance with claim ~~462~~, wherein said feeding means comprises a mechanical resistance (R) and a mechanical capacitance (C) circuit

146

resulting in an exponentially decaying outflow of medication for each said fixed volume pulse.

367 380
451. A programmable infusion system in accordance with claim 451, further comprising means for telemetering operational information pertaining to said infusion apparatus out of said living body, and means for receiving said telemetered operational information external to said living body, wherein said infusion means further comprises an outlet chamber which is in communication with said living body, said pump means expelling said selected medication into said outlet ^{chamber} means; and means for monitoring the operation of said pump means, said monitoring means being disposed in said outlet chamber and providing a signal in response to a pressure pulse in said outlet chamber caused by said pump means, said monitoring means being operably coupled to said telemetry means.

D1 381
380 465. A programmable infusion system in accordance with claim 464, wherein said monitoring means comprises a pressure transducer.

382
380 466. A programmable infusion system in accordance with claim 464, further comprising first means for indicating the operation of said pump means when a decrease in volume of said variable volume means is not followed by a signal from said monitoring means corresponding to a pressure pulse of said selected medication expelled into said outlet chamber, said first indicating means being operably coupled to said telemetry means.

383
382 467. A programmable infusion system in accordance with claim 466, further comprising second means for indicating the operation of said pump means when a signal is provided by said monitoring means absent a decrease in volume of said variable volume means

E ~~caused by said moving means~~, said second indicating means being operably coupled to said telemetry means.

363 384
468. A programmable infusion system in accordance with claim 447, further comprising means for telemetering operational information pertaining to said infusion apparatus out of said living body, means for receiving said telemetered operational information external to said living body, and means for monitoring the operation of said pump means, said monitoring means being operably coupled to said telemetry means.

385
364 469. A programmable infusion system in accordance with claim 468, wherein said monitoring means comprises pressure sensing means disposed in the path of flow of said selected medication into said living body, said pressure sensing means providing a signal in response to a pressure pulse in said path of flow.

CLAIMS Sub E 28
386 387 470. A programmable infusion system in accordance with claim 469, further comprising first means for indicating the operation of said pump means when a decrease in volume of said variable volume means is not followed by a signal from said monitoring means corresponding to a pressure pulse of said selected medication expelled into said outlet chamber, said first indicating means being operably coupled to said telemetry means.

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387
386 471. A programmable infusion system in accordance with claim 470, further comprising second means for indicating the operation of said pump means when a signal is provided by said monitoring means absent a decrease in volume of said variable volume means ~~caused by said moving means~~, said second indicating means being operably coupled to said telemetry means.

✓ 384 388
412. A programmable infusion system in accordance with claim
412, said infusion apparatus further comprising means for
generating a distinctive alarm signal pattern for each of a
plurality of improper ^{operational} operation conditions.

COMB E 29
384-398
yellow
472. A programmable infusion system in accordance with claim
472, wherein said alarm signal ^{is delivered} ~~is delivered~~ to said living body
subcutaneously. ^{pattern}

474. A programmable infusion system in accordance with claim
473, further comprising means for detecting a medication leak,
coupled to said alarm means, wherein one of said improper
operation ^{generating} conditions comprises a medication leak out of said
medication reservoir.

475. A programmable infusion system in accordance with claim
473, further comprising means for detecting a body fluid leak,
coupled to said alarm means, wherein one of said improper
operation ^{generating} conditions comprises a leak of body fluids into said
infusion apparatus.

476. A programmable infusion system in accordance with claim
473, further comprising means for detecting the rate at which
said infusion means is operating, ^{said rate detecting means being} coupled to said alarm means,
wherein one of said improper operation ^{generating} conditions comprises
operation of said infusion means at an improper rate.

477. A programmable infusion system in accordance with claim
473, wherein one of said improper operation ^{receiving} conditions comprises
receiving of a command by said command receiver ^{which cannot be}
executed.

478. A programmable infusion system in accordance with claim 473, further comprising ^{or} battery means for powering said infusion means and means for determining the voltage of said battery ^{means}, coupled to said alarm ^{voltage determination means being} means, wherein one of said improper operation ^{at} conditions ^{generating} comprises low battery ^{means} voltage.

479. A programmable infusion system in accordance with claim 473, further comprising means for detecting the ^{amount} of medication disposed in said reservoir, ^{said medication amount detecting means being} coupled to said alarm means, wherein one of said improper operation ^{at} conditions ^{generating} comprises a preselected amount of medication remaining in said medication reservoir.

480. A programmable infusion system in accordance with claim 472, further comprising means for detecting a medication leak, ^{said medication detecting means being} coupled to said alarm means, wherein one of said improper operation ^{at} conditions ^{generating} comprises a medication leak out of said medication reservoir.

481. A programmable infusion system in accordance with claim 472, further comprising means for detecting a body fluid leak, ^{said body fluid detecting means being} coupled to said alarm means, wherein one of said improper operation ^{at} conditions ^{generating} comprises a leak of body fluids into said infusion apparatus.

482. A programmable infusion system in accordance with claim 472, further comprising means for detecting the rate at which said infusion means is operating ^{said rate detecting means being} coupled to said alarm means, wherein one of said improper operation ^{at} conditions ^{generating} comprises operation of said infusion means at an improper rate.

389 483. A programmable infusion system in accordance with claim 472, wherein one of said improper ^{operational} operation ^{at} conditions comprises

ε receiving of a command by said command receiver ^{means} which cannot be executed.

Sub E 30

CLAIMS

400-405

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484. A programmable infusion system in accordance with claim 472, further comprising ^a battery means for powering said infusion means and means for determining the voltage of said battery ^{means}, ^{said voltage determining means being} coupled to said alarm means, wherein one of said improper operation ^{generating} condition ^{means} comprises low battery ^{means} voltage.

485. A programmable infusion system in accordance with claim 472, further comprising means for detecting the amount of ^{said medication amount detecting means being} medication disposed in said reservoir ^a coupled to said alarm means, wherein one of said improper operation ^{generating} conditions comprises a preselected amount of medication remaining in said medication reservoir.

K 388

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486. A programmable infusion system in accordance with claim 472, further comprising means for simulating said improper operational conditions for test purposes.

N 328

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487. A programmable infusion system in accordance with claim 472, wherein said infusion means includes means for pumping a preselected amount of medication into said living body, said infusion apparatus further comprising means for recording the rate at which ^{the} pumping is effected by said pumping means.

ε 328

Sub E 31

488. A programmable infusion system in accordance with claim 487, wherein said recording means comprises:
means for storing the rate at which said pumping means pumps over a preselected time period;
means for storing a programmable input corresponding to a minimum medication infusion rate; and

156

means for comparing the rate recorded by said ^{first recited} recording means to the rate stored in said ^{second recited} storing means.

489. A programmable infusion system in accordance with claim 488, further comprising means for providing an alarm signal when said rate recorded by said ^{first recited} recording means is less than said ^{programmable} minimum medication infusion rate. ^{input corresponding to said} ^{recorded by said second recited storing means.}

406 ~~489~~. A programmable infusion system in accordance with claim ~~488~~, further comprising means for telemetering information ^{recorded} deduced by said recording means out of said living body, said telemetry means being coupled to said recording means, and means for receiving said telemetered information external to said living body.

407 ~~491~~. A programmable infusion system in accordance with claim ~~487~~, wherein said recording means comprises:

^{D/E} ^E P_1 means for storing the rate at which said ^{pump} ~~pumping~~ means pumps over a preselected time period; and P_2 means for storing the rate at which said ^{pump} ~~pumping~~ means is signalled to pump over said preselected time period.

408 ~~492~~. A programmable infusion system in accordance with claim ~~491~~, further comprising means for comparing the rates recorded by both said storing means.

409 ~~493~~. A programmable infusion system in accordance with claim ~~492~~, further comprising means for telemetering information ^{outputted} ~~deduced~~ by said comparing means out of said living body, said comparing means being coupled to said telemetry means, and means for receiving said telemetered information external to said living body.

408 410
492. A programmable infusion system in accordance with claim
492, further comprising means for providing an alarm signal when
the rate at which said ^{pump} ~~pumping~~ means pumps is different than the
rate at which said ^{pump} ~~pumping~~ means ^{is} ~~is~~ signalled to pump.

407 411
491. A programmable infusion system in accordance with claim
491, further comprising means for telemetering information
recorded by ~~both~~ said recording means out of said living body,
~~both~~ said recording means being coupled to said telemetry means,
and means for receiving said telemetered information external to
said living body.

403 412
496. A programmable infusion system in accordance with claim
497, wherein said pump means executes in pulses, said recording
means comprising a pulse rate detector comprising:
P₁ means for counting the number of times said ^{pump} ~~pumping~~ means
pumps over a preselected time period, said counting means
storing the count;

P₂ minimum rate memory means for storing a programmable number
input corresponding to a minimum medication infusion rate; and
P₃ means for comparing the number counted by said counting
means with said programmable number input stored in said minimum
rate memory means.

413 413
497. A programmable infusion system in accordance with claim
497, further comprising means for providing an alarm signal when
said count is less than said programmable number input stored in
said minimum rate memory means.

414
413 498. A programmable infusion system in accordance with claim
497, wherein said alarm signal comprises a subcutaneous
electrical stimulation.

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413 416
499. A programmable infusion system in accordance with claim
497, wherein said counting means comprises a pressure
transducer.

E 413 416
500. A programmable infusion system in accordance with claim
497, further comprising means for telemetering information
~~deduced~~ ^{outputted} by said comparing means out of said living body, said
comparing means being coupled to said telemetry means, and means
for receiving said telemetered operational information external
to said living body.

413 417
501. A programmable infusion system in accordance with claim
497, wherein said pump means executes in pulses, said recording
means comprising a pulse recorder comprising:

E P
D1 means for counting the number of times said ~~pump~~ ^{pump} means
pumps over a preselected time period, said counting means
storing the count; and

E P
means for counting the number of times said ~~pump~~ ^{pump} means is
commanded to pump over said preselected time period.

E 413 418
417 502. A programmable infusion system in accordance with claim
501, wherein said pulse recorder further comprises means for
comparing the ~~number~~ ^{numbers} recorded by both said counting means.

E 413 419
503. A programmable infusion system in accordance with claim
502, further comprising means for telemetering information
~~deduced~~ ^{outputted} by said comparing means out of said living body, said
comparing means being coupled to said telemetry means, and means
for receiving said telemetered information external to said
living body.

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420
504. A programmable infusion system in accordance with claim
417
501, further comprising means for providing an alarm signal when
said numbers recorded by both said counting means are different.

421
420 505. A programmable infusion system in accordance with claim
504, wherein said alarm signal comprises a subcutaneous
electrical stimulation.

422
417 506. A programmable infusion system in accordance with claim
501, further comprising means for telemetering information
recorded by both said counting means out of said living body,
said recording means being coupled to said telemetry means, and
means for receiving said telemetered information external to
said living body.

423
D1 417 507. A programmable infusion system in accordance with claim
501, wherein said first recited counting means comprises a
pressure transducer.

424
328 508. A programmable infusion system in accordance with claim
417, further comprising means for maintaining the pressure
within said medication reservoir at a pressure level below the
internal pressure of said living body.

425
424 509. A programmable infusion system in accordance with claim
508, wherein said pressure maintaining means comprises:
P a flexible diaphragm which divides said medication reservoir
into a medication chamber and a liquid-vapor pool chamber; and
P a liquid vapor pool disposed within said liquid-vapor pool
chamber, the proportion of liquid to vapor in said liquid-vapor
pool varying in response to variations in the amount of said
selected medication disposed in said medication chamber.

425-426

510. A programmable infusion system in accordance with claim 509, further comprising means for telemetering operational information pertaining to said infusion apparatus out of said living body, and means for receiving said telemetered operational information external to said living body, said infusion apparatus further comprising switch means disposed within said medication reservoir, said switch means being coupled to said telemetry means and being activated when said flexible diaphragm is disposed in a preselected relationship relative to said switch means, said telemetry means telemetering a signal indicative of such an operational condition to said telemetry receiving means.

427

511. A programmable infusion system in accordance with claim 510 wherein said switch means is activated by pressure exerted thereon by said flexible diaphragm, said pressure being less than the ambient pressure of said body.

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428

512. A programmable infusion system in accordance with claim 509, said infusion apparatus further comprising an antechamber through which access is gained to said medication reservoir, and a reservoir inlet valve located between said antechamber and said medication chamber, said reservoir inlet valve being operable ~~and~~ when the pressure in said antechamber exceeds the pressure in ^{said medication} ~~the reservoir~~ chamber by more than a predetermined differential.

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E

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513. A programmable infusion system in accordance with claim 512, wherein the volume of said antechamber is less than 10% the volume of said ^{medication} ~~reservoir~~ chamber.

E

430

514. A programmable infusion system in accordance with claim 512, further comprising an inlet filter means operably disposed

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between said antechamber and said medication chamber for preventing impurities in said selected medication in said antechamber from passing into said medication chamber when said reservoir inlet valve is opened, said filter means also preventing said selected medication in said medication chamber from rapidly entering said living body in the event of a leak in said inlet valve.

✓ 431
430⁵¹⁵. A programmable infusion system in accordance with claim 412, further comprising means for programmed pumping of fixed-volume pulses of medication into said living body.

✓ 432
430⁵¹⁶. A programmable infusion system in accordance with claim 412, further comprising means for telemetering operational information pertaining to said infusion apparatus out of said living body, means for receiving said telemetered operational information external to said living body, and means for injecting medication into said medication reservoir, said injecting means being coupled to said telemetry receiver means, and programming means coupled to said telemetry means for indicating when injection of medication into said medication reservoir is appropriate.

ε ✓ 433
430⁵¹⁷. A programmable infusion system for providing medication to a living body ^{of a patient} comprising:

P₁ An infusion apparatus for implantation in said living body, said apparatus including
P₂ a medication reservoir for storing selected medication,
P₂ means for infusing said selected medication stored in said medication reservoir into said living body, said infusion means having at least one remotely commandable operational characteristic.

P command receiver means coupled to said infusion means for receiving command signals, and

E *P* means for generating a distinctive alarm signal pattern for each of a plurality of improper ^{operational} ~~operation~~ conditions in said system; and

P command source means external to said living body for transmitting said command signals to be received by said command receiver means.

Sub E 32
COATMS
134-416
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D *N* 518. A programmable infusion system in accordance with claim 517, wherein said alarm signal is ^{further comprising means for delivering} ~~is delivered~~ to said living body subcutaneously. ^{Pattern}

D *N* 519. A programmable infusion system in accordance with claim 518, further comprising means for detecting a medication leak, ^{medication detecting means being} coupled to said alarm means, wherein one of said improper operation ^{generating} ~~al~~ conditions comprises a medication leak out of said medication reservoir.

E
say body 520. A programmable infusion system in accordance with claim 518, further comprising means for detecting a body fluid leak, ^{fluid detecting means being} coupled to said alarm means, wherein one of said improper operation ^{generating} ~~al~~ conditions comprises a leak of body fluids into said infusion apparatus.

D 521. A programmable infusion system in accordance with claim 518, further comprising means for detecting the rate at which said infusion means is operating, ^{said rate detecting means being} coupled to said alarm means, wherein one of said improper operation ^{generating} ~~al~~ conditions comprises operation of said infusion means at an improper rate.

522. A programmable infusion system in accordance with claim 518, wherein one of said improper operation^{al} conditions comprises receiving of a command by said command receiver^{means} which cannot be executed.

523. A programmable infusion system in accordance with claim 518, further comprising^a battery means for powering said infusion means and means for determining the voltage of said battery^{means}, coupled to said alarm means^{voltage determining means being}, wherein one of said improper operation^{al} conditions^{generating} comprises low battery^{means} voltage.

524. A programmable infusion system in accordance with claim 518, further comprising means for detecting the amount of medication disposed in said reservoir^{said medication amount detecting means being}, coupled to said alarm^{generating} means^{al}, wherein one of said improper operation^{al} conditions comprises a preselected amount of medication remaining in said medication reservoir.

525. A programmable infusion system in accordance with claim 517, further comprising means for detecting a medication leak, said medication^{detecting means being} coupled to said alarm^{generating} means^{al}, wherein one of said improper operation^{al} conditions^{generating} comprises a medication leak out of said medication reservoir.

526. A programmable infusion system in accordance with claim 517, further comprising means for detecting a body fluid leak, said body^{fluid detecting means being} coupled to said alarm means^{al}, wherein one of said improper operation^{al} conditions^{generating} comprises a leak of body fluids into said infusion apparatus.

527. A programmable infusion system in accordance with claim 517, further comprising means for detecting the rate at which said infusion means is operating^{said rate detecting means being}, coupled to said alarm means,

wherein one of said improper operation^{al} conditions comprises operation of said infusion means at an improper rate.

528. A programmable infusion system in accordance with claim 517, wherein one of said improper operation^{al} conditions comprises receiving of a command by said command receiver^{means} which cannot be executed.

529. A programmable infusion system in accordance with claim 517, further comprising^a battery means for powering said infusion means and means for determining the voltage of said battery^{means}, coupled to said alarm^{detecting means being} means, wherein one of said improper operation^{al} conditions^{generating} comprises low battery^{means} voltage.

530. A programmable infusion system in accordance with claim 517, further comprising means for detecting the amount of medication disposed in said reservoir^{said medication detecting means being}, coupled to said alarm^{generating} means, wherein one of said improper operation^{al} conditions comprises a preselected amount of medication remaining in said ~~medication reservoir.~~

447
433
531. A programmable infusion system in accordance with claim 517, further comprising means for simulating said improper operational conditions for test purposes.

448
433
532. A programmable infusion system in accordance with claim 517, wherein one of said command signals transmitted by said command source means comprises a signal which corresponds to a selected operational rate at which said infusion means will infuse said selected medication into said living body.

449
433
533. A programmable infusion system in accordance with claim 517, further comprising means for telemetering operational

information pertaining to said infusion apparatus out of said living body, and means for receiving said telemetered operational information external to said living body, wherein said command source and said telemetry receiving means are embodied in a patient programming unit external to said living body, said patient programming unit having a plurality of operational medication dose inputs each corresponding to a medication infusion rate selectable and requestable by the patient, said patient programming unit for selectively transmitting a command signal corresponding to a selected ^{one of} said medication dose ^{inputs} ~~input~~.

450
449 534. A programmable infusion system in accordance with claim 533, wherein said infusion apparatus further comprises electronic control means coupled to said infusion means and said command receiver means, said ^{electronic} ~~electric~~ control means ^{including means} for maintaining a history of the infusion rate at which said infusion means has operated, said ^{including means} ~~electronic~~ control means for precluding the infusion of said selected medication by said infusion means if said rate requested by said patient programming unit exceeds a predetermined safe medication infusion rate based on said maintained history.

451
450 535. A programmable infusion system in accordance with claim 534, wherein said electronic control means is coupled to said telemetry means, said patient programming unit including means for indicating to said patient if said selected infusion rate exceeds said predetermined safe medication infusion rate, said ^{electronic} ~~selective~~ control means selectively sending a signal to said indicating means via said telemetry means and said telemetry receiving means, said telemetry receiving means being coupled to said indicating means.

452
450 536. A programmable infusion system in accordance with claim
534, wherein said patient programming unit further comprises
annunciator means and visual display means for providing
information regarding previously selected medication infusion
rates, for indicating whether a proper programming of a
presently requested infusion rate has been communicated to said
command receiver, and for selectively providing information as
to the time and rate of previously selected medication infusion.

✓ 43 453
43 537. A programmable infusion system in accordance with claim
517, further comprising means for selectively supplying power to
said command receiver means, said supply means being coupled to
an external power source, said supply means being external to
said living body, said infusion means being powered by an
implanted power source.

D1 454
538. A programmable infusion system, in accordance with
claim 537, wherein said supply means provides an alternating
field.

455
454 539. A programmable infusion system, in accordance with
claim 538, wherein said infusion apparatus further comprises
detector means for detecting said alternating field and for
converting the same into electrical energy, said detecting means
being coupled to said command receiver.

456
455 540. A programmable infusion system in accordance with claim
539, wherein said infusion apparatus further comprises means for
rectifying said electrical energy into a d.c. power signal.

457
541. A programmable infusion system in accordance with
claim 540, wherein said d.c. power signal is coupled to said
implanted power source to effect the charging thereof.

171

458
456 542. A programmable infusion system in accordance with claim
540, further comprising means for telemetering operational
information pertaining to said infusion apparatus out of said
living body, and means for receiving said telemetered
operational information external to said living body, said
telemetry means being coupled to said rectifier means and being
powered by said d.c. power signal.

459
453 543. A programmable infusion system in accordance with
claim 537, further comprising means for telemetering operational
information pertaining to said infusion apparatus out of said
living body, and means for receiving said telemetered
operational information external to said living body, said
telemetry means also being supplied power by said supply means.

D1 460
455 544. A programmable infusion system in accordance with claim
537, further comprising means for selectively recharging said
implanted power source, said recharging means being powered by
said supply means.

461
433 545. A programmable infusion system in accordance with claim
517, wherein said infusion means comprises a fluid handling
mechanism for delivering said selected medication, said
operational information including information about the
operation of said fluid handling mechanism.

462
461 546. A programmable infusion system in accordance with claim
545, wherein said fluid handling mechanism comprises means for
pumping said selected medication.

CLAIM 833
163 on 547. A programmable infusion system in accordance with claim
546, wherein the amount of medication pumped by said pumping
means is controlled by a pressure limit in said pump means.

172

✓ 464
463 548. A programmable infusion system in accordance with claim
548, wherein said pump means operates in a pulsatile mode.

✓ 465
464 549. A programmable infusion system in accordance with claim
548, wherein said pump means pumps a fixed volume of said
selected medication each time said pump means is pulsed.

✓ 466
463 550. A programmable infusion system in accordance with claim
548, wherein said pump means comprises variable volume means for
storing said selected medication within said pump means, an
increase in volume of said variable volume means permitting
drawing of said selected medication into said pump means, ^a
decrease in volume of said variable volume means permitting
expulsion of said selected medication from said pump means.

CLAIMS
467-472

✓ 467
468 551. A programmable infusion system in accordance with claim
550, wherein said variable volume means comprises at least one
flexible wall, movement of said ^{at least one} flexible wall varying the volume
of said variable volume means, and means for moving said ^{at least one}
flexible wall.

✓ 468
469 552. A programmable infusion system in accordance with claim
551, further comprising spring means for urging said ^{at least one flexible} wall in a
manner which decreases the volume of said variable volume means,
the magnitude of the force applied to and stored by said spring
means increasing as the volume of said variable volume means
increases due to the displacement of said ^{at least one} flexible wall thereof
by said moving means.

✓ 469
470 553. A programmable infusion system in accordance with claim
552, wherein said ^{at least one} flexible wall comprises a bellows assembly
having mounted on one end thereof a plate, the other end of said
bellows ^{assembly} being in communication with said selected medication,
the walls of said bellows ^{assembly} serving as said spring means.

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466
554. A programmable infusion system in accordance with claim
553, wherein said plate has a surface in contact with said
selected medication when drawn into said variable volume means.

471
555. A programmable infusion system in accordance with claim
470 554, wherein said bellows ^{assembly} is inhibited from moving said plate
when the pressure (p) in said variable volume means exceeds the
spring force (F) of said bellows ^{assembly} divided by the wetted area (A)
of said surface of said plate in contact with said selected
medication, that is when $p > \frac{F}{A}$.

535
556. A programmable infusion system in accordance with claim
553, wherein said ~~moving means comprises~~ said plate ^{is} being
magnetizable, ~~and~~ ^{said moving means comprising} a coil disposed proximate to said plate, said
coil selectively radiating a pulsing magnetic field, pulsing of
said coil causing said plate to be moved.

473
557. A programmable infusion system in accordance with claim
556, wherein said plate comprises a permanent magnet.

474
473
558. A programmable infusion system in accordance with claim
553, further comprising means for limiting the distance said
plate can move in both ^a the volume increasing direction and ^a the
volume decreasing direction.

475
466
559. A programmable infusion system in accordance with claim
550, wherein said infusion means further comprises:

2
P₁ an interface pressure ^{valve} ~~value~~ through which said selected
medication enters said variable volume means from said
medication reservoir, said interface pressure ^{valve} ~~value~~ being
normally closed;
P₁ an outlet chamber which is in communication with said living
body; and

P an outlet pressure valve located between said variable volume means and said outlet chamber, said outlet pressure valve being normally closed, an increase in volume of said variable volume means causing said interface pressure valve to open and medication to enter said variable volume means, a decrease in volume of said variable volume means causing said outlet pressure valve to open and said interface pressure valve to close, so as to permit medication to enter said outlet chamber as a pressure pulse.

E 475 ⁴⁷⁶ 560. A programmable infusion system in accordance with claim 559, wherein said outlet chamber comprises an elastic wall having a fluidic capacitive effect on the flow of said selected medication and a filter element through which liquid flow to the said ^{living} ~~lining~~ body is resisted, said elastic wall and said filter comprising a fluid resistance - capacitance arrangement with respect to said flow of said selected medication from said outlet chamber into said living body.

DI E 464 ⁴⁷⁷ 561. A programmable infusion system in accordance with claim 560, further comprising means for feeding said selected medication into said living body from said pump means in a flow which decays exponentially over time.

477 ⁴⁷⁸ 562. A programmable infusion system in accordance with claim 561, wherein said feeding means comprises a mechanical resistance (R) and a mechanical capacitance (C) circuit resulting in an exponentially decaying outflow of medication for each said fixed volume pulse.

479 ⁴⁸⁰ 563. A programmable infusion system in accordance with claim 562, further comprising means for telemetering operational information pertaining to said infusion apparatus out of said

living body, and means for receiving said telemetered
operational information, ~~extended~~ ^{external} to said living body, wherein said
infusion means further comprises an outlet chamber which is in
communication with said living body, said pump means expelling
said selected medication into said outlet ~~means~~ ^{chamber}, and means for
monitoring the operation of said pump means, said monitoring
means being disposed in said outlet chamber and providing a
signal in response to a pressure pulse in said outlet chamber
caused by said pump means, said monitoring means being operably
coupled to said telemetry means.

479 ⁴⁸⁰ 564. A programmable infusion system in accordance with claim
563, wherein said monitoring means comprises a pressure
transducer.

D1 479 ⁴⁸¹ 565. A programmable infusion system in accordance with claim
563, further comprising first means for indicating the operation
of said pump means when a decrease in volume of said variable
volume means is not followed by a signal from said monitoring
means corresponding to a pressure pulse of said selected
medication expelled into said outlet chamber, said first
indicating means being operably coupled to said telemetry means.

481 ⁴⁸² 566. A programmable infusion system in accordance with claim
565, further comprising second means for indicating the operation
of said pump means when a signal is provided by said monitoring
means absent a decrease in volume of said variable volume means
~~caused by said moving means~~, said second indicating means being
operably coupled to said telemetry means.

✓ 482 ⁴⁸³ 567. A programmable infusion system in accordance with claim
566, further comprising means for telemetering operational
information pertaining to said infusion apparatus out of said

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living body, ~~and~~ ^{information} means for receiving said telemetered operational ~~inclusion~~ external to said living body, and means for monitoring the operation of said pump means, said monitoring means being operably coupled to said telemetry means.

⁴⁸⁴
~~485~~ 566. A programmable infusion system in accordance with claim 567, wherein said monitoring means comprises pressure sensing means disposed in the path of flow of said selected medication into said living body, said pressure sensing means providing a signal in response to a pressure pulse in said path of flow.

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569. A programmable infusion system in accordance with claim 568, further comprising first means for indicating the operation of said pump means when a decrease of volume of said variable volume means is ~~not~~ followed by a signal from said monitoring means corresponding to a pressure pulse of said selected medication expelled into said outlet chamber, said first indicating means being operably coupled to said telemetry means.

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⁴⁸⁶
~~485~~ 570. A programmable infusion system in accordance with claim 569 further comprising second means for indicating the operation of said pump means when a signal is provided by said monitoring means ^{absent} ~~about~~ a decrease in volume of said variable volume means ~~caused by said moving means~~, said second indicating means being operably coupled to said telemetry means.

~~485~~ 571. A programmable infusion system in accordance with claim 517, wherein one of said ^{at least one} remotely commandable operational characteristics comprises an infusion rate variable on command, said infusion apparatus further comprising means for inhibiting said infusion means from infusing said selected medication if a preselected medication infusion rate is exceeded, said inhibiting means being operably coupled to said infusion means.

^{by a commanded infusion rate}

81

487⁴⁸⁸ 572. A programmable infusion system in accordance with claim 571, wherein said inhibiting means comprises at least one means for defining a fixed infusion rate limit.

E 488⁴⁸⁹ 573. A programmable infusion system in accordance with claim 572, wherein said ^{at least one} means for defining a fixed infusion rate limit is hardwired.

487⁴⁹⁰ 574. A programmable infusion system in accordance with claim 571, wherein said preselected medication infusion rate is remotely selectable.

487⁴⁹¹ 575. A programmable infusion system in accordance with claim 571, wherein said preselected medication infusion rate comprises a remotely selectable rate and a fixed rate, said remotely selectable rate being limited by said fixed rate.

576. A programmable infusion system in accordance with claim 575, wherein said inhibiting means comprises:

at least one programmable rate memory unit coupled to said command receiver means, each of said ^{at least one} programmable rate memory units for receiving and storing a infusion rate input command corresponding to said remotely selectable rate;

at least one limit control unit, each of ^{said at least one limit control unit providing} which provides a fixed rate limit; and

means for comparing each of said infusion rate input commands to a corresponding said fixed rate limit, infusion of said medication at a rate exceeding said fixed rate limit being inhibited.

E 492⁴⁹³ 576. A programmable infusion system in accordance with claim 575, further comprising command decoder means for coupling ^{each of} said at least one ~~said~~ programmable rate memory ^{unit} to said command

receiver means, said command decoder means for decoding said
command signals received by said command receiver means into
said infusion rate inputs for receipt by and storage in said at
least one programmable rate memory ^{units} ~~unit~~. ^{corresponding}

494
492 578. A programmable infusion system in accordance with claim
576, wherein each of said ^{at least one} limit control units ^{is} ~~are~~ hardwired.

495
492 579. A programmable infusion system in accordance with claim
576, further comprising means for generating an alarm signal
when any infusion rate input command exceeds a corresponding
fixed rate limit.

496
492 580. A programmable infusion system in accordance with claim
578, wherein said inhibiting means precludes infusion of said
medication by said infusion means when the selected said
commandable infusion rate exceeds said preselected medication
infusion rate during a ~~fixed~~ window ^{of a predetermined length} of time which shifts
continuously.

497
492 581. A programmable infusion system in accordance with claim
577 wherein said inhibiting means precludes infusion of said
medication by said infusion means when the selected said
commandable infusion rate exceeds ^{medication} said preselected infusion rate
during a ~~fixed~~ window ^{of a predetermined length} of time which shifts continuously.

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582. A programmable infusion system in accordance with claim
571, wherein said infusion means includes a pump means which
executes in pulses, said inhibiting means comprising a
programmable memory ^{rate unit} coupled to said command receiver
for storing initially a ^{dose limit} number corresponding to a first maximum
number of infusion pulses preselected as allowable during a
first shifting ~~maximum~~ time window of a predetermined length,

pulse quantities being subtracted from said number stored in said programmable memory rate unit as infusion pulses are executed by said infusion means, pulse quantities being added to said stored number as time elapses such that said number does not exceed said first maximum number, said subtraction and addition being accomplished in running integral fashion, said inhibiting means not permitting pulsing of said pump means ~~a~~ ^{at a rate} ~~number of times~~ in excess of said ^{dose limit} number stored in said programmable memory rate unit.

D1 583. A programmable infusion system in accordance with claim 582, wherein said memory rate unit also records the number of pulses which have been inhibited and causes said pump means of said infusion means to execute said pulses when said pulses can be subtracted ^{as a result of the lapse of time} from said number stored in said programmable memory rate unit. ^{dose limit}

584. A programmable infusion system in accordance with claim 582, wherein said programmable memory rate unit also stores initially another ^{dose limit} number corresponding to a second maximum number of infusion pulses preselected as allowable during a second shifting time window of a predetermined length, said second shifting time window being longer in length than said first shifting time window, pulse quantities being subtracted from said another ^{dose limit} number stored in said programmable memory rate unit as infusion pulses are executed by said infusion means, pulse quantities being added to said another ^{dose limit} number as time elapses such that said another ^{dose limit} number does not exceed said first maximum number, said subtraction and addition being accomplished in running integral fashion, said inhibiting means not permitting pulsing of said pump means ^{at a rate} ~~a number of times~~ in excess of ^{the rate represented by dose limit} said another ^{dose limit} number stored in said programmable memory ~~rate unit.~~

⁵⁰¹
~~585~~ 585. A programmable infusion system in accordance with claim
⁵⁶⁰
~~584~~, wherein said rate memory unit also records the number of
pulses which have been inhibited and causes said pump means of
said infusion means to execute said pulses when said pulses can
be subtracted from ^{both said dose limit} ~~said~~ numbers stored in said programmable
memory rate unit. [^]

⁵⁰²
~~586~~ 586. A programmable infusion system in accordance with claim
⁵⁰¹
~~585~~, wherein said inhibiting means further comprises at least
one fixed infusion rate limit which limits the total maximum
infusion rate of said infusion means.

⁵⁰³
~~587~~ 587. A programmable infusion system in accordance with claim
⁵⁰²
~~586~~, wherein said fixed infusion rate limit is hardwired.

⁵⁰⁴
~~588~~ 588. A programmable infusion system in accordance with claim
⁵⁰¹
~~584~~, further comprising means for generating an alarm signal
when any commanded infusion rate results in the inhibiting of
pulsing of said pump means by said inhibiting means.

⁵⁰⁵
~~589~~ 589. A programmable infusion system in accordance with claim
⁵⁰⁴
~~588~~, wherein said alarm signal comprises a subcutaneous
electrical stimulation.

⁵⁰⁶
~~590~~ 590. A programmable infusion system in accordance with claim
⁵⁶⁰
~~584~~, further comprising command decoder means for coupling said
command receiver means to said programmable memory rate unit,
said command decoder means for decoding said command signals
received by said command receiver means into said first and
second ^{maximum} numbers of infusion pulses. [^]

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507
467-591. A programmable infusion system in accordance with claim 591, further comprising means for telemetering operational information pertaining to said infusion apparatus out of said living body, said operational information including information pertaining to the functions of said inhibiting means, and means for receiving said telemetered operational information external to said living body.

508
433-592. A programmable infusion system in accordance with claim 592, wherein said infusion means includes means for pumping a preselected amount of medication into said living body, said infusion apparatus further comprising means for recording the rate at which pumping is effected by said ^{pump} ~~pumping~~ means.

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594-511
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592. A programmable infusion system in accordance with claim 592, wherein said recording means comprises:
means for storing the rate at which said ~~pumping~~ means pumps over a preselected time period;
means for storing a programmable input corresponding to a minimum medication infusion rate; and
means for comparing the rate recorded by said ^{first recited} ~~recording~~ means to the rate stored in said ^{second recited} ~~storing~~ means.

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594. A programmable infusion system in accordance with claim 593, further comprising means for providing an alarm signal when said rate recorded by said recording means is less than said ^{input corresponding to said} ~~programmable~~ minimum medication infusion rate.
^{recorded by said second recited storing means.}

511
509-595. A programmable infusion system in accordance with claim 595, further comprising means for telemetering ^{recorded} ~~deduced~~ information out of said living body, said telemetry means being coupled to said recording means and means for receiving said telemetered ^{information} ~~injection~~ external to said living body.

⁵¹²
~~506~~ 596. A programmable infusion system in accordance with claim
~~592~~, wherein said recording means comprises:

ε P₁ means for storing the rate at which said ^{pump}~~pumping~~ means pumps
over a preselected time period; and

ε P₁ means for storing the rate at which said ^{pump}~~pumping~~ means is
signalled to pump over said preselected time period.

⁵¹³
~~512~~ 597. A programmable infusion system in accordance with claim
~~596~~, further comprising means for comparing the rates recorded
by both said storing means.

⁵¹⁴
~~513~~ 598. A programmable infusion system in accordance with claim
~~597~~, further comprising means for telemetering information
ε ^{outputted}~~deduced~~ by said comparing means out of said living body, said
comparing means being coupled to said telemetry means, and means
for receiving said telemetered information external to said
living body.

D1
⁵¹⁵
~~513~~ 599. A programmable infusion system in accordance with claim
~~597~~, further comprising means for providing an alarm signal when
ε the rate at which said ^{pump}~~pumping~~ means pumps is different than the
ε rate at which said ^{pump}~~pumping~~ means ^{is}~~is~~ signalled to pump.

⁵¹⁶
~~512~~ 600. A programmable infusion system in accordance with claim
~~596~~, further comprising means for telemetering information
ε recorded by ~~both~~ said recording means out of said living body,
ε ~~both~~ said recording means being coupled to said telemetry means,
and means for receiving said telemetered information external to
said living body.

⁵¹⁷
~~508~~ 601. A programmable infusion system in accordance with claim
~~592~~, wherein said pump means executes in pulses, said recording
means comprising a pulse rate detector comprising:

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E P₁ means for counting the number of times said ^{pump}~~pumping~~ means pumps over a preselected time period, said counting means storing the count;
P₁ minimum rate memory means for storing a programmable number input corresponding to a minimum medication infusion rate; and
P₁ means for comparing the number counted by said counting means with said programmable number input stored in said minimum rate memory means.

⁵¹⁸
~~517~~⁵¹⁸~~501~~ 502. A programmable infusion system in accordance with claim 501, further comprising means for providing an alarm signal when said count is less than said programmable number input stored in said minimum rate memory means.

⁵¹⁹
~~518~~⁵¹⁹~~502~~ 503. A programmable infusion system in accordance with claim 502, wherein said alarm signal comprises a subcutaneous electrical stimulation.

D1 ⁵²⁰
~~518~~⁵²⁰~~502~~ 504. A programmable infusion system in accordance with claim 502, wherein said counting means comprises a pressure transducer.

⁵²⁰
~~518~~⁵²⁰~~502~~ 505. A programmable infusion system in accordance with claim 502, further comprising means for telemetering information ^{outputted}~~deduced~~ by said comparing means out of said living body, said comparing means being coupled to said telemetry means, and means for receiving said telemetered operational information external to said living body.

⁵²¹
~~508~~⁵²¹~~502~~ 506. A programmable infusion system in accordance with claim 502, wherein said pump means executes in pulses, said recording means comprising a pulse recorder comprising:

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E ⁵²³₆₀₇ means for counting the number of times said ^{pump}~~pumping~~ means pumps over a preselected time period, said counting means storing the count; and

E ⁵²⁴₆₀₈ means for counting the number of times said ^{pump}~~pumping~~ means is commanded to pump over said preselected time period.

⁵²³₆₀₇. A programmable infusion system in accordance with claim ⁵²⁴₆₀₈, wherein said pulse recorder further comprises means for comparing the ~~number~~ recorded by both said counting means.

E ⁵²⁴₆₀₈. A programmable infusion system in accordance with claim ⁵²⁵₆₀₉, further comprising means for telemetering information ^{outputted}~~deduced~~ by said comparing means out of said living body, said comparing means being coupled to said telemetry means, and means for receiving said telemetered information external to said living body.

D1 ⁵²⁵₆₀₉. A programmable infusion system in accordance with claim ⁵²⁶₆₁₀, further comprising means for providing an alarm signal when said numbers recorded by both said counting means are different.

⁵²⁶₆₁₀. A programmable infusion system in accordance with claim ⁵²⁷₆₁₁, wherein said alarm signal comprises a subcutaneous electrical stimulation.

⁵²⁷₆₁₁. A programmable infusion system in accordance with claim ⁵²⁸₆₁₂, further comprising means for telemetering information recorded by both said counting means out of said living body, said recording means being coupled to said telemetry means, and means for receiving said telemetered information external to said living body.

⁵²⁸
~~522~~ ⁵²⁸ 512. A programmable infusion system in accordance with claim
~~506~~, wherein said first recited counting means comprises a
pressure transducer.

⁵²⁹
~~438~~ ⁵²⁹ 513. A programmable infusion system in accordance with claim
~~517~~, further comprising means for maintaining the pressure
within said medication reservoir at a pressure level below the
internal pressure of said living body.

⁵³⁰
~~529~~ ⁵³⁰ 514. A programmable infusion system in accordance with claim
~~513~~, wherein said pressure maintaining means comprises:

*P*₁ a flexible diaphragm which divides said medication reservoir
into a medication chamber and a liquid-vapor pool chamber; and
*P*₁ a liquid vapor pool disposed within said liquid-vapor pool
chamber, the proportion of liquid to vapor in said liquid-vapor
pool varying in response to variations in the amount of said
selected medication disposed in said medication chamber.

D1

⁵³¹
~~530~~ ⁵³¹ 515. A programmable infusion system in accordance with claim
~~514~~, further comprising means for telemetering operational
information pertaining to said infusion apparatus out of said
living body, and means for receiving said telemetered
operational information external to said living body, said
infusion apparatus further comprising switch means disposed
within said medication reservoir, said switch means being
coupled to said telemetry means and being activated when said
flexible diaphragm is disposed in a preselected relationship
relative to said switch means, said telemetry means telemetering
a signal indicative of such an operational condition to said
telemetering receiving means.

E ⁵³²
~~531~~ ⁵³² 516. A programmable infusion system in accordance with claim
~~515~~, wherein said switch means is activated by pressure exerted

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thereon by said flexible diaphragm, said pressure being less than the ambient pressure of said body.

⁵³³
~~536~~⁵¹⁷. A programmable infusion system in accordance with claim ~~614~~, said infusion apparatus further comprising an antechamber through which access is gained to said medication reservoir, and a reservoir inlet valve located between said antechamber and said medication chamber, said reservoir inlet valve being operable ~~and~~ when the pressure in said antechamber exceeds the pressure in the ^{said medication} ~~reservoir~~ chamber by more than a predetermined differential.

⁵³⁴
~~533~~⁶¹⁸. A programmable infusion system in accordance with claim ~~617~~, wherein the volume of said antechamber is less than 10% the volume of said ^{medication} ~~reservoir~~ chamber.

⁵³⁵
~~534~~⁶¹⁹. A programmable infusion system in accordance with claim ~~617~~, further comprising an inlet filter means operably disposed between said antechamber and said medication chamber for preventing impurities in said selected medication in said antechamber from passing into said medication chamber when said reservoir inlet valve is opened, said filter means also preventing said selected medication in said medication chamber from rapidly entering said living body in the event of a leak in said inlet valve.

⁵³⁶
~~534~~⁶²⁰. A programmable infusion system in accordance with claim ~~617~~, further comprising means for programmed pumping of fixed-volume pulses of medication into said living body.

⁵³⁷
~~534~~⁶²¹. A programmable infusion system in accordance with claim ~~617~~, further comprising means for telemetering operational information pertaining to said infusion apparatus out of said

living body, means for receiving said telemetered operational information external to said living body, and means for injecting medication into said medication reservoir, said injecting means being coupled to said telemetry receiver means, and programming means coupled to said ^{telemetry} ~~telemetering~~ means for indicating when injection of medication into said medication reservoir is appropriate.

538
622. A programmable infusion system for providing medication to a living body ^{of a patient} comprising:

P₁ an infusion apparatus for implantation in said living body, said apparatus including

P₂ a medication reservoir for storing selected medication,

P₂ means for infusing said selected medication stored in said medication reservoir into said living body, said infusion means having at least one remotely commandable operational characteristic and including means for pumping a preselected amount of medication into said living body,

P₂ means for recording the rate at which pumping is effected by said ^{pump} ~~pumping~~ means, and

P₂ command receiver means coupled to said infusion means for receiving command signals; and

P₁ command source means external to said living body for transmitting said command signals to be received by said command receiver means.

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539-540
623. A programmable infusion system in accordance with claim 622, wherein said recording means comprises:

means for ^{scoring} ~~scoring~~ the rate at which said ^{pumping} ~~pumping~~ means pumps over a preselected time period;

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L
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P means for storing a programmable input corresponding to a minimum medication infusion rate; and

means for comparing the rate recorded by said ^{first recited storing} recording means to the rate stored in said ^{second recited} storing means.

624. A programmable infusion system in accordance with claim 623, further comprising means for providing an alarm signal when said rate recorded by said ^{first recited storing} recording means is less than said programmable ^{input corresponding to said} minimum medication infusion rate. ^{recorded by said second recited storing means.}

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539
E 625. A programmable infusion system in accordance with claim 623, further comprising means for telemetering information ^{recorded} deduced by said recording means out of said living body, said telemetry means being coupled to said recording means, and means for receiving said telemetered information external to said living body.

D1
542
E 626. A programmable infusion system in accordance with claim 538
E 622, wherein said recording means comprises:
P₁ means for storing the rate at which said ^{pump} ~~pumping~~ means pumps over a preselected time period; and
P₁ means for storing the rate at which said ^{pump} ~~pumping~~ means is signalled to pump over said preselected time period.

543
627. A programmable infusion system in accordance with claim 542
542 626, further comprising means for comparing the rates recorded by both said storing means.

544
543
E 628. A programmable infusion system in accordance with claim 627, further comprising means for telemetering information ^{outputted} deduced by said comparing means out of said living body, said comparing means being coupled to said telemetry means, and means for receiving said telemetered information external to said living body.

545
629. A programmable infusion system in accordance with claim
543
627, further comprising means for providing an alarm signal when
the rate at which said ^{pump}~~pumping~~ means pumps is different than the
rate at which said ^{pump}~~pumping~~ means ^{is}~~is~~ signalled to pump.

546
630. A programmable infusion system in accordance with claim
542
628, further comprising means for telemetering information
recorded by ~~both~~ said recording means out of said living body,
~~both~~ said recording means being coupled to said telemetry means,
and means for receiving said telemetered information external to
said living body.

547
631. A programmable infusion system in accordance with claim
538
622, wherein said pump means executes in pulses, said recording
means comprising a pulse rate detector comprising:
D² 1 P₁ means for counting the number of times said ^{pump}~~pumping~~ means
pumps over a preselected time period, said counting means
storing the count;
P₁ minimum rate memory means for storing a programmable number
input corresponding to a minimum medication infusion rate; and
P₁ means for comparing the number counted by said counting
means with said programmable number input stored in said minimum
rate memory means.

548
632. A programmable infusion system in accordance with claim
547
631, further comprising means for providing an alarm signal when
said count is less than said programmable number input stored in
said minimum rate memory means.

549
633. A programmable infusion system in accordance with claim
548
632, wherein said alarm signal comprises a subcutaneous
electrical stimulation.

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⁵⁵⁰
~~548~~ 634. A programmable infusion system in accordance with claim
~~632~~, wherein said counting means comprises a pressure
transducer.

⁵⁵¹
~~548~~ 635. A programmable infusion system in accordance with claim
E ~~632~~, further comprising means for telemetering information
^{outputted}
~~deduced~~ by said comparing means out of said living body, said
comparing means being coupled to said telemetry means, and means
for receiving said telemetered operational information external
to said living body.

✓ ⁵⁵²
~~538~~ 636. A programmable infusion system in accordance with claim
~~622~~, wherein said pump means executes in pulses, said recording
means comprising a pulse recorder comprising:

D/E P₁ means for counting the number of times said ^{pump}~~pumping~~ means
pumps over a preselected time period, said counting means
storing the count; and

E P₁ means for counting the number of times said ^{pump}~~pumping~~ means is
commanded to pump over said preselected time period.

↓ ⁵⁵³
E ~~552~~ 637. A programmable infusion system in accordance with claim
~~636~~, wherein said pulse recorder further comprises means for
comparing the ^{numbers}~~number~~ recorded by both said counting means.

⁵⁵⁴
~~553~~ 638. A programmable infusion system in accordance with claim
E ~~637~~, further comprising means for telemetering information
^{outputted}
~~deduced~~ by said comparing means out of said living body, said
comparing means being coupled to said telemetry means, and means
for receiving said telemetered information external to said
living body.

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✓ 552 ⁵⁵⁵
~~554~~ 639. A programmable infusion system in accordance with claim
~~636~~, further comprising means for providing an alarm signal when
said numbers recorded by both said counting means are different.

⁵⁵⁶
~~555~~ 640. A programmable infusion system in accordance with claim
~~639~~, wherein said alarm signal comprises a subcutaneous
electrical stimulation.

✓ ⁵⁵⁷
~~554~~ 641. A programmable infusion system in accordance with claim
~~636~~, further comprising means for telemetering information
recorded by both said counting means out of said living body,
said recording means being coupled to said telemetry means, and
means for receiving said telemetered information external to
said living body.

✓ ⁵⁵⁸
~~554~~ 642. A programmable infusion system in accordance with claim
~~636~~, wherein said first recited counting means comprises a
pressure transducer.

D1 ⁵⁵⁹
~~538~~ 643. A programmable infusion system in accordance with claim
~~622~~, wherein one of said command signals transmitted by said
command source means comprises a signal which corresponds to a
selected operational rate at which said infusion means will
infuse said selected medication into said living body.

⁵⁶⁰
~~538~~ 644. A programmable infusion system in accordance with claim
~~622~~, further comprising means for telemetering operational
information pertaining to said infusion apparatus out of said
living body, and means for receiving said telemetered
operational information external to said living body, wherein
said command source and said telemetry receiving means are
embodied in a patient programming unit external to said living
body, said patient programming unit having a plurality of

operational medication dose inputs each corresponding to a medication infusion rate selectable and requestable by the patient, said patient programming unit for selectively transmitting a command signal corresponding to a selected ^{one of} said medication dose ^{input} ~~input~~.

⁵⁶¹
~~560~~ 645. A programmable infusion system in accordance with Claim 644, wherein said infusion apparatus further comprises electronic control means coupled to said infusion means and said command receiver means, said ^{electronic} ~~electric~~ control means ^{including means} for maintaining a history of the infusion rate at which said infusion means has operated, said ^{including means} ~~electric~~ control means for precluding the infusion of said selected medication by said infusion means if said rate requested by said patient programming unit exceeds a predetermined safe medication infusion rate based on said maintained history.

D1 ⁵⁶²
~~561~~ 646. A programmable infusion system in accordance with claim 645, wherein said electronic control means is coupled to said telemetry means, said patient programming unit including means for indicating to said patient if said selected infusion rate exceeds said predetermined safe medication infusion rate, said ^{electric} ~~selective~~ control means selectively sending a signal to said indicating means via said telemetry means and said telemetry receiving means, said telemetry receiving means being coupled to said indicating means.

⁵⁶³
~~561~~ 647. A programmable infusion system in accordance with claim 645, wherein said patient programming unit further comprises annunciator means and visual display means for providing information regarding previously selected medication infusion rates, for indicating whether a proper programming of a presently requested infusion rate has been communicated to said

command receiver, and for selectively providing information as to the time and rate of previously selected medication infusion.

⁵⁶⁴
~~648~~ 538. A programmable infusion system in accordance with claim ~~622~~, further comprising means for selectively supplying power to said command receiver means, said supply means being coupled to an external power source, said supply means being external to said living body, said infusion means being powered by an implanted power source.

⁵⁶⁵
~~649~~ 564. A programmable infusion system, in accordance with claim ~~648~~, wherein said supply means provides an alternating field.

⁵⁶⁶
~~650~~ 565. A programmable infusion system, in accordance with claim ~~649~~, wherein said infusion apparatus further comprises detector means for detecting said alternating field and for converting the same into electrical energy, said detecting means being coupled to said command receiver.

⁵⁶⁷
~~651~~ 566. A programmable infusion system in accordance with claim ~~650~~, wherein said infusion apparatus further comprises means for rectifying said electrical energy into a d.c. power signal.

⁵⁶⁸
~~652~~ 567. A programmable infusion system in accordance with claim ~~651~~, wherein said d.c. power signal is coupled to said implanted power source to effect the charging thereof.

⁵⁶⁹
~~653~~ 568. A programmable infusion system in accordance with claim ~~652~~, further comprising means for telemetering operational information pertaining to said infusion apparatus out of said living body, and means for receiving said telemetered operational information external to said living body, said

telemetry means being coupled to said rectifier means and being powered by said d.c. power signal.

⁵⁷⁰~~654~~. A programmable infusion system in accordance with claim ⁵⁶⁴~~648~~, further comprising means for telemetering operational information pertaining to said infusion apparatus out of said living body, and means for receiving said telemetered operational information external to said living body, said telemetry means also being supplied power by said supply means.

⁵⁷¹~~655~~. A programmable infusion system in accordance with claim ⁵⁶⁴~~648~~, further comprising means for selectively recharging said implanted power source, said recharging means being powered by said supply means.

⁵⁷²~~656~~. A programmable infusion system in accordance with claim ⁵³⁸~~622~~, wherein said infusion means comprises a fluid handling mechanism, said fluid handling mechanism including said pump means, said operational information including information about the operation of said fluid handling mechanism.

⁵⁷³~~657~~. A programmable infusion system in accordance with claim ⁵⁷⁵~~656~~, wherein the amount of medication pumped by said pump means is controlled by a pressure limit in the said pump means.

⁵⁷⁴~~658~~. A programmable infusion system in accordance with claim ⁵⁷³~~656~~, wherein said pump means operates in a pulsatile mode. ✓

⁵⁷⁵~~659~~. A programmable infusion system in accordance with claim ⁵⁷⁴~~658~~, wherein said pump means pumps a fixed volume of said selected medication each time said pump means is pulsed.

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660. A programmable infusion system in accordance with claim 656, wherein said pump ^{mean} comprises variable volume means for storing said selected medication within said pump means, ^{at least one,} an increase in volume of said variable volume means permitting drawing of said selected medication into said pump means, a decrease in volume of said variable volume means permitting expulsion of said selected medication from said pump means.

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661. A programmable infusion system in accordance with claim 660, wherein said variable volume means comprises at least one flexible wall, movement of said flexible wall varying the volume of said variable volume means ^{at least one}, and means for moving said ^{at least one} flexible wall.

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662. A programmable infusion system in accordance with claim 661, further comprising spring means for urging said ^{at least one flexible} wall in a manner which decreases the volume of said variable volume means, the magnitude of the force applied to and stored by said spring means increasing as the volume of said variable volume means increases due to the displacement of said ^{at least one} flexible wall thereof by said moving means.

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663. A programmable infusion system in accordance with claim 662, wherein said ^{at least one} flexible wall comprises a bellows assembly having mounted on one end thereof a plate, the other end of said bellows ^{assembly} being in communication with said selected medication, the walls of said bellows ^{assembly} serving as said spring means.

664. A programmable infusion system in accordance with claim 663, wherein said plate has a surface in contact with said selected medication when drawn into said variable volume means.

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665. A programmable infusion system in accordance with claim
664, wherein said bellows ^{assembly} is inhibited from moving said plate
when the pressure (p) in said variable volume means exceeds the
spring force (F) of said bellows ^{assembly} divided by the wetted area (A)
of said surface of said plate in contact with said selected
medication, that is when $p > \frac{F}{A}$.

Sub E44
666. A programmable infusion system in accordance with claim
563, wherein said moving means comprises said plate being ^{is}
magnetizable, and a coil disposed proximate to said plate, said
coil selectively radiating a pulsing magnetic field, pulsing of
said coil causing said plate to be moved.

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667. A programmable infusion system in accordance with claim
582, wherein said plate comprises a permanent magnet.

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D1 583
668. A programmable infusion system in accordance with claim
583, further comprising means for limiting the distance said
plate can move in both ^a the volume increasing direction and ^a the
volume decreasing direction.

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669. A programmable infusion system in accordance with claim
668, wherein said infusion means further comprises:
P₁ an interface pressure ^{valve} through which said selected
medication enters said variable volume means from said
medication reservoir, said interface pressure valve being
normally closed;
P₁ an outlet chamber which is in communication with said living
body; and
P₁ an outlet pressure valve located between said variable
volume means and said outlet chamber, said outlet pressure valve
being normally closed, an increase in volume of said variable
volume means causing said interface pressure valve to open and

medication to enter said variable volume means, a decrease in volume of said variable volume means causing said outlet pressure valve to open and said interface pressure valve to close, so as to permit medication to enter said outlet chamber as a pressure pulse.

586
585 ~~670~~. A programmable infusion system in accordance with claim ~~669~~, wherein said outlet chamber comprises an elastic wall having a fluidic capacitive effect on the flow of said selected medication and a filter element through which liquid flow to the said ^{living} ~~lining~~ body is resisted, said elastic wall and said filter comprising a fluid resistance - capacitance arrangement with respect to said flow of said selected medication from said outlet chamber into said living body.

587
D/E 585 ~~671~~. A programmable infusion system in accordance with claim ~~669~~, further comprising means for feeding said selected medication into said living body from said pump means in a flow which decays exponentially over time.

588
586 ~~672~~. A programmable infusion system in accordance with claim ~~670~~, wherein said feeding means comprises a mechanical resistance (R) and a mechanical capacitance (C) circuit resulting in an exponentially decaying outflow of medication for each said fixed volume pulse.

589
586 ~~673~~. A programmable infusion system in accordance with claim ~~660~~, further comprising means for telemetering operational information pertaining to said infusion apparatus out of said living body, and means for receiving said telemetered operational information ^{external} ~~extended~~ to said living body, wherein said infusion means further comprises an outlet chamber which is in communication with said living body, said pump means

8 expelling said selected medication into said outlet ^{chambers, ✓} means; and 8
means for monitoring the operation of said pump means, said
monitoring means being disposed in said outlet chamber and
E ^{providing} providing a signal in response to a pressure pulse in said outlet
chamber caused by said pump means, said monitoring means being
operably coupled to said telemetry means.

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589-674. A programmable infusion system in accordance with claim
673, wherein said monitoring means comprises a pressure
transducer.

591
589-675. A programmable infusion system in accordance with claim
673, further comprising first means for indicating the operation
of said pump means when a decrease in volume of said variable
volume means is not followed by a signal from said monitoring
means corresponding to a pressure pulse of said selected
medication expelled into said outlet chamber, said first
indicating means being operably coupled to said telemetry means.

D1
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591-676. A programmable infusion system in accordance with claim
675, further comprising second means for indicating the operation
of said pump means when a signal is provided by said monitoring
means absent a decrease in volume of said variable volume means
E ~~caused by said monitoring means~~, said second indicating means being
operably coupled to said telemetry means.

593 ✓
✓ 582
572 591-677. A programmable infusion system in accordance with claim
676, further comprising means for telemetering operational
E information pertaining to said infusion apparatus out of said
living body, and means for receiving said telemetered
E operational ^{information} ~~infusion~~ external to said living body, and means for
monitoring the operation of said pump means, said monitoring
means being operably coupled to said telemetry means.

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594
678. A programmable infusion system in accordance with claim
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677, wherein said monitoring means comprises pressure sensing
means disposed in the path of flow of said selected medication
into said living body, said pressure sensing means providing a
signal in response to a pressure pulse in said path of flow.

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595-596
679. A programmable infusion system in accordance with claim
678, further comprising first means for indicating the operation
of said pump means when a decrease in volume of said variable
volume means is not followed by a signal from said monitoring
means corresponding to a pressure pulse of said selected
medication expelled into said outlet chamber, said first
indicating means being operably coupled to said telemetry means.

594
595
680. A programmable infusion system in accordance with claim
679, further comprising second means for indicating the
operation of said pump means when a signal is provided by said
monitoring means absent a decrease in volume of said variable
volume means ~~caused by said moving means~~, said second indicating
means being operably coupled to said telemetry means.

591
594
681. A programmable infusion system in accordance with claim
680, wherein one of said ~~characteristic~~ ^{at least one} remotely commandable operational
~~characteristic~~ comprises an infusion rate variable on command,
said infusion apparatus further comprising means for inhibiting
said infusion means from infusing said selected medication if a
preselected medication infusion rate is exceeded, said
inhibiting means being operably coupled to said infusion means.

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682. A programmable infusion system in accordance with claim
681, wherein said inhibiting means comprises at least one means
for defining a fixed infusion rate limit.

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E 683. A programmable infusion system in accordance with claim
682, wherein said ^{at least one} means for defining a fixed infusion rate limit
is hardwired.

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684. A programmable infusion system in accordance with claim
681, wherein said preselected medication infusion rate is
remotely selectable.

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685. A programmable infusion system in accordance with claim
681, wherein said preselected medication infusion rate comprises
a remotely selectable rate and a fixed rate, said remotely
selectable rate being limited by said fixed rate.

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686. A programmable infusion system in accordance with claim
682, wherein said inhibiting means comprises:
at least one programmable rate memory unit coupled to said
command receiver means, each of said ^{at least one} programmable rate memory
units for receiving and storing ^{data} an infusion rate input command
corresponding to said remotely selectable rate;
at least one limit control unit, each of ^{said at least one limit control} which provides a ^{unit providing}
fixed rate limit; and
means for comparing each of said infusion rate input
commands to a corresponding said fixed rate limit, infusion of
said medication at a rate exceeding said fixed rate limit being
~~inhibited.~~

603
E 602
E 687. A programmable infusion system in accordance with claim
686, further comprising command decoder means for coupling ^{each of} said
at least one ~~said~~ programmable rate memory ^{units} ~~unit~~ to said command
receiver means, said command decoder means for decoding said
command signals received by said command receiver means into
E said infusion rate inputs for receipt by and storage in ^{corresponding} said at
least one programmable rate memory unit.

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E 688. A programmable infusion system in accordance with claim 686, wherein each of said ^{at least on} limit control units ^{is} ~~are~~ hardwired.

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689. A programmable infusion system in accordance with claim 686, further comprising means for generating an alarm signal when any infusion rate input command exceeds a corresponding fixed rate limit.

✓ 606
605
E 690. A programmable infusion system in accordance with claim 689, wherein said inhibiting means precludes infusion of said medication by said infusion means when the selected said commandable infusion rate exceeds said preselected medication infusion rate during a ~~fixed~~ ^{of a predetermined} window of time which shifts continuously.

DI 607
E 691. A programmable infusion system in accordance with claim 597, wherein said inhibiting means precludes infusion of said medication by said infusion means when the selected said commandable infusion rate exceeds said ^{medication} preselected infusion rate ^{of a predetermined length} during a ~~fixed~~ window of time which shifts continuously.

CLAIMS E47
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P
692. A programmable infusion system in accordance with claim 681, wherein said pump means executes in pulses, said inhibiting means comprising a programmable memory rate unit coupled to said command receiver for storing initially a ^{discrete} number corresponding to a first maximum number of infusion pulses preselected as allowable during a first shifting time window of a predetermined length, pulse quantities being subtracted from said number stored in said programmable memory rate unit as infusion pulses are executed by said infusion means, pulse quantities being added to said stored number as time elapses such that said number does not exceed said first maximum number, said subtraction and addition being accomplished in running integral

fashion, said inhibiting means not permitting pulsing of said pump means ^{at a rate} ~~a number of times~~ ^{the rate represented by} in excess of said number stored in said programmable memory rate unit. ^{dose limit}

693. A programmable infusion system in accordance with claim 692, wherein said memory rate unit also records the number of pulses which have been inhibited and causes said pump means of said infusion means to execute said pulses when said pulses can be subtracted from said ^{dose limit} ~~number~~ stored in said programmable memory rate unit as a result of the elapse of time.

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P
694. A programmable infusion system in accordance with claim 692, wherein said programmable memory rate unit also stores initially another ^{dose limit} ~~number~~ corresponding to a second maximum number of infusion pulses preselected as allowable during a second shifting time window of a predetermined length, said second shifting time window being longer in length than said first shifting time window, pulse quantities being subtracted from said another ^{dose limit} ~~number~~ stored in said programmable memory rate unit as infusion pulses are executed by said infusion means; pulse quantities being added to said ^{dose limit} ~~another stored~~ number as time elapses such that said ^{dose limit} ~~another~~ number does not exceed said first maximum number, said subtraction and addition being accomplished in running integral fashion, said inhibiting means not permitting pulsing of said pump means ^{at a rate} ~~a number of times~~ in excess of said ^{dose limit} ~~another~~ number stored in said programmable memory ~~rate unit~~.

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695. A programmable infusion system in accordance with claim 694, wherein said rate memory unit also records the number of pulses which have been inhibited and causes said pump means of said infusion means to execute said pulses when said pulses can be subtracted from said ^{dose limit} ~~numbers~~ stored in said programmable memory rate unit.
E

⁶¹²
~~611~~ 696. A programmable infusion system in accordance with claim
~~695~~, wherein said inhibiting means further comprises at least
one fixed infusion rate limit which limits the total maximum
infusion rate of said infusion means.

⁶¹³
~~612~~ 697. A programmable infusion system in accordance with claim
~~696~~, wherein said fixed infusion rate limit is hardwired.

⁶¹⁴ ✓
~~613~~ 698. A programmable infusion system in accordance with claim
~~697~~, further comprising means for generating an alarm signal
when any commanded infusion rate results in the inhibiting of
pulsing of said pump means by said inhibiting means.

⁶¹⁵
~~614~~ 699. A programmable infusion system in accordance with claim
~~698~~, wherein said alarm signal comprises a subcutaneous
electrical stimulation.

D1

⁶¹⁶
~~610~~ 700. A programmable infusion system in accordance with claim
~~699~~, further comprising command decoder means for coupling said
command receiver means to said programmable memory rate unit,
said command decoder means for decoding said command signals
received by said command receiver means into said first and
second ^{maximum} numbers of infusion pulses.

E

⁶¹⁷
~~538~~ 701. A programmable infusion system in accordance with claim
~~699~~, further comprising means for telemetering operational
information pertaining to said infusion apparatus out of said
living body, said operational information including information
pertaining to the functions of said inhibiting means, and means
for receiving said telemetered operational information external
to said living body.

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622. A programmable infusion system in accordance with claim
said infusion apparatus further comprising means for
generating a distinctive alarm signal pattern for each of a
plurality of improper ^{operationally} ~~operation~~ conditions.

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703. A programmable infusion system in accordance with claim
702, wherein said alarm signal ^{is delivered} ~~is delivered~~ to said living body
subcutaneously.

704. A programmable infusion system in accordance with claim
703, further comprising means for detecting a medication leak,
^{said medication detecting means being} coupled to said alarm means, wherein one of said improper
operation conditions comprises a medication leak out of said
medication reservoir.

DK
705. A programmable infusion system in accordance with claim
703, further comprising means for detecting a body fluid leak,
^{said detecting means being} coupled to said alarm means, wherein one of said improper
operation ^{at} conditions ^{generating} comprises a leak of body fluids into said
infusion apparatus.

706. A programmable infusion system in accordance with claim
703, further comprising means for detecting the rate at which
said infusion means is operating, ^{said rate detecting means being} coupled to said alarm means,
wherein one of said improper operation conditions ^{generating} comprises
operation of said infusion means at an improper rate.

707. A programmable infusion system in accordance with claim
703, wherein one of said improper operation ^{at} conditions comprises
receiving of a command by said command receiver ^{means} which cannot be
executed.

231

708. A programmable infusion system in accordance with claim 703, further comprising ^a battery means for powering said infusion means and means for determining the voltage of said battery ~~means~~, ^{voltage determination means being} coupled to said alarm ^{means}, wherein one of said improper operation ^{al} conditions ^{generating} comprises low battery ^{means} voltage.

709. A programmable infusion system in accordance with claim 703, further comprising means for detecting the amount of ^{said medication amount detecting means being} medication disposed in said reservoir, coupled to said alarm means wherein one of said improper operation ^{al} conditions ^{generating} comprises a preselected amount of medication remaining in said medication reservoir.

710. A programmable infusion system in accordance with claim 702, further comprising means for detecting a medication leak, ^{said medication detecting means being} coupled to said alarm ^{means}, wherein one of said improper operation ^{al} conditions ^{generating} comprises a medication leak out of said ~~medication reservoir~~.

711. A programmable infusion system in accordance with claim 702, further comprising means for detecting a body fluid leak, ^{said body fluid detecting means being} coupled to said alarm means wherein one of said improper operation conditions comprises a leak of body fluids into said infusion apparatus.

712. A programmable ^S infusion system in accordance with claim 702, further comprising means for detecting the rate at which ^{said rate detecting means being} said infusion means is operating, coupled to said alarm ^{means}, wherein one of said improper operation ^{al} conditions ^{generating} comprises operation of said infusion means at an improper rate.

713. A programmable infusion system in accordance with claim 702, wherein one of said improper operation ^{al} conditions comprises

receiving of a command by said command receiver^{means} which cannot be executed.

714. A programmable infusion system in accordance with claim 702, further comprising^a battery means for powering said infusion means and means for determining the voltage of said battery^{means},^{said voltage determining means being} coupled to said alarm means, wherein one of said improper operation^{al} conditions^{is detecting} comprises low battery^{means} voltage.

715. A programmable infusion system in accordance with claim 702, further comprising means for detecting the amount of medication disposed in said reservoir^{said medication amount detecting means being} coupled to said alarm^{means} wherein one of said improper operation^{al} conditions^{is generating} comprises a preselected amount of medication remaining in said ~~medication reservoir.~~

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716. A programmable infusion system in accordance with claim 702, further comprising means for simulating said improper operational conditions for test purposes.

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717. A programmable infusion system in accordance with claim 702, further comprising means for maintaining the pressure within said medication reservoir at a pressure level below the internal pressure of said living body.

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633
718. A programmable infusion system in accordance with claim 717, wherein said pressure maintaining means comprises:
P₁ a flexible diaphragm which divides said medication reservoir into a medication chamber and a liquid-vapor pool chamber; and
P₁ a liquid vapor pool disposed within said liquid-vapor pool chamber, the proportion of liquid to vapor in said liquid-vapor pool varying in response to variations in the amount of said selected medication disposed in said medication chamber.

⁶³⁵
~~715~~ 635. A programmable infusion system in accordance with claim
⁶³⁴
~~718~~ further comprising means for telemetering operational
information pertaining to said infusion apparatus out of said
living body, and means for receiving said telemetered
operational information external to said living body, said
infusion apparatus further comprising switch means disposed
within said medication reservoir, said switch means being
coupled to said telemetry means and being activated when said
flexible diaphragm is disposed in a preselected relationship
relative to said switch means, said telemetry means telemetering
a signal indicative of such an operational condition to said
telemetry receiving means.

⁶³⁶
⁶³⁵ ~~720~~ 635. A programmable infusion system in accordance with claim
D1 ~~719~~ wherein said switch means is activated by pressure exerted
thereon by said flexible diaphragm, said pressure being less
than the ambient pressure of said body.

⁶³⁷
⁶³⁴ ~~721~~ 634. A programmable infusion system in accordance with claim
E ~~718~~ said infusion apparatus further comprising an antechamber
E through which access is gained to said medication reservoir, and
a reservoir inlet valve located between said antechamber and
said medication chamber, said reservoir inlet valve being
operable ~~and~~ when the pressure in said antechamber exceeds the
pressure in ^{said medication} ~~the reservoir~~ chamber by more than a predetermined
differential.

⁶³⁸
⁶³⁷ ~~722~~ 637. A programmable infusion system in accordance with claim
E ~~721~~ wherein the volume of said antechamber is less than 10% the
volume of said ^{medication} ~~reservoir~~ chamber. B

⁶³⁹
⁶³⁸ ~~723~~ 638. A programmable infusion system in accordance with claim
~~721~~ further comprising an inlet filter means operably disposed

between said antechamber and said medication chamber for preventing impurities in said selected medication in said antechamber from passing into said medication chamber when said inlet valve is opened, said filter means also preventing said ~~reservoir~~ ^{reservoir} selected medication in said medication chamber from rapidly entering said living body in the event of a leak in said inlet valve.

⁶⁴⁰
~~535~~ ⁷²⁴. A programmable infusion system in accordance with claim ~~622~~, further comprising means for programmed pumping of fixed-volume pulses of medication into said living body.

⁶⁴¹
~~535~~ ⁷²⁵. A programmable infusion system in accordance with claim ~~622~~, further comprising means for telemetering operational information pertaining to said infusion apparatus out of said living body, and means for receiving said telemetered operational information external to said living body, and means for injecting medication into said medication reservoir, said injecting means being coupled to said ~~telemetering~~ ^{telemetry} receiver means, and programming means coupled to said ~~telemetering~~ ^{telemetry} means for indicating when injection of medication into said medication reservoir is appropriate.

⁶⁴²
~~535~~ ⁷²⁶. A programmable infusion system in accordance with claim ~~622~~, further comprising means for injecting medication into said medication reservoir, said injecting means being coupled to said ~~telemetering~~ ^{telemetry} receiver means, and programming means coupled to said ~~telemetering~~ ^{telemetry} means for indicating when ejection of medication into said medication reservoir is appropriate.

END

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